(54) Title: ENDOSCOPIC ULTRASONIC ASPIRATOR WITH MODIFIED WORKING TIP
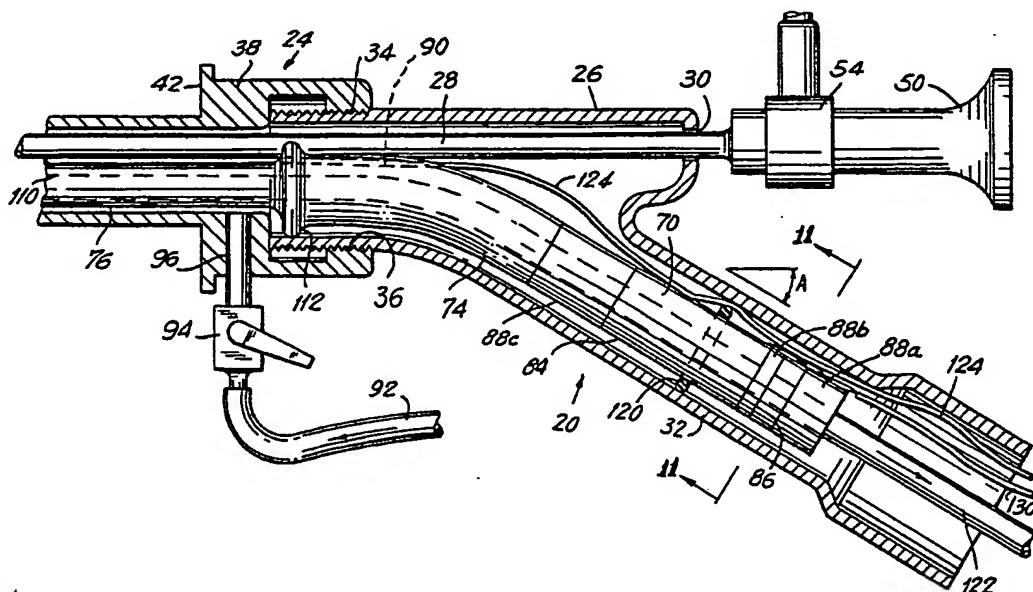
(57) Abstract

A method and apparatus for endoscopic removal of compliant biological tissues utilizing an endoscopic ultrasonic aspirator comprising irrigation (94) and aspiration (122) means, a piezoelectric ultrasonic transducer (70), a first resonator (72) such as a half-wave stepped velocity transformer, a probe including a second resonator (78) such as a constant-stress velocity transformer, a blunt or modified working tip (80) of open channel means or restricted tubular means for application of ultrasonic energy to cellular material, and a capacitive fluid sensor (124) to detect the presence of irrigation fluid adjacent these transforms within the instrument. The surgery is advantageously performed by operating the transducer in the 10-20 KHz range to achieve maximum cavitation of the intracellular fluids in the tissues to be removed.

ENDOSCOPIC ULTRASONIC ASPIRATOR
WITH MODIFIED WORKING TIP

BACKGROUND OF THE INVENTION

Field of the Invention

5   The invention relates to a method and apparatus for
removing unwanted biological tissue. It relates more
particularly to surgery using an endoscopic ultrasonic
aspirator with an elongated hollow probe and simultaneous
irrigation and aspiration, which disintegrates and removes
10   highly compliant tissue from deep within the body through a
narrow surgical orifice.

Description of Related Art

          The endoscopic ultrasonic aspirator (hereinafter
15   "EUA") of the present invention is particularly useful in the
field of transurethral resection (TUR) of the prostate gland
or other urological surgery, including destruction and
removal of bladder stones. More generally, it is useful in
any type of surgery in which deep penetration of the body
20   through a narrow orifice is required, for example
arthroscopic surgery, diskectomy, or other orthopedic
surgery.
          In a preferred embodiment of the invention, an
ultrasonic probe with a high peak tip velocity is insertable
25   at least about 19 cm into the body for disintegrating
compliant tissues, simultaneously irrigating the operating
site, and aspirating fluid and tissue, through a surgical
orifice no more than about 29 mm in circumference, which is
the accepted maximum dimension for an instrument to be
30   inserted into the urethra. The circumference of the
instrument may be as great as about 29 mm, but preferably is
no more than about 25 mm.
          A unit of measurement known as the French is fre-
quently used to denote circumferential size. A sheath size
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in French is three times the sheath's diameter in milli-
meters. Thus, a sheath having a circumference of 30 mm has a
diameter of $30/\pi$ = 9.55 and a French size of 9.55 x 3 =
28.65.

5   Since the 1950's TUR has been the procedure of
choice for removal of the diseased prostate gland. In one
conventional procedure, the patient is placed in the
conventional lithotomy position under spinal anesthesia. An
elongated resectoscope with a light source, a telescope, a
10 cutting electrode, and a source of continuous irrigation is
inserted into the urethra and advanced to the vicinity of the
prostate gland, where access to the prostate is gained
through the urethral wall. The cutting electrode is a
semicircular wire mounted at the end of a slidable shaft for
15 antegrade and retrograde motion; that is, toward the front
and rear of the patient. The electrode is supplied with a
pulsed RF current which both cuts and cauterizes tissue. The
shaft is spring-biased toward the rear of the patient and is
repetitively drawn forward by a trigger-like lever as the
20 electrode slices off small slivers of prostate tissue.

As the tissue is sliced off it is washed into the
bladder by the continuous irrigation, which fills the bladder
about every 5 minutes. The accumulated water and debris must
be removed periodically with a suction device such as the
25 Ellik evacuator, which has a squeeze bulb coupled to a
flexible plastic catheter. The resectoscope is removed, the
bulb is compressed and the plastic catheter is inserted to
the operative site. Then the bulb is expanded to draw out
the water and tissue debris.

30   This traditional procedure has a number of
disadvantages that the present invention is intended to
avoid. In order for the surgeon to view the operating site,
the EUA must be provided with some type of viewing and
lighting system. It has been found that, at the present
35 level of optical technology, an adequate endoscopic view of
surgical procedures requires an optical relay lens system

that uses lenses with a diameter of about 2.5 mm. Since
these lenses must be mounted within a rigid tube that also
contains illumination fibers, the total diameter of the
finished telescope typically measures about 4 mm. Addition-
ally, in order for a hollow ultrasonic tip to remove firm
prostatic tissue at an adequate rate (typically from about 5
to about 10 grams per minute), the bore of the tip must also
be about 4 mm.

In an endoscopic aspirator, both the telescope and
the tip are placed side by side within a sheath. When the
endoscopic aspirator is inserted into a patient's body, the
sheath protects the surrounding tissue from contacting the
ultrasonic tip which vibrates not only at its surgical
extremity but also along its entire length.

The use of a loop-shaped electrode for cutting
requires antegrade cutting so that removed tissue does not
build up in front of the loop and block the viewing lens.
However, with antegrade cutting, the loop is always hidden
under some thickness of tissue. This leads to the risk that
the surgeon's view will be blocked and the urinary sphincter,
the bladder wall, or even the intestines may be accidentally
damaged. The surgeon can also pierce the prostate capsule,
which is the tougher outer skin of the prostate, and injure
the blood vessels beyond. Electrical cutting is very fast,
so these can occur even with the exercise of due care.
Further when the telescope of the EUA is positioned adjacent
to the ultrasonic tip, the walls of the ultrasonic tip
interfere with the surgeon's view of the operating site.

Also, evacuation must be performed 10 to 20 times,
removing the resectoscope each time, and this may take up as
much as 20 to 50 percent of the one-hour operating time.

Another disadvantage of the prior procedure is that
the continuous irrigation flow described above causes filling
and distention of the bladder and absorption of the fluid
into the blood, leading to the danger of hypervolemia or
hyponatremia. Also, electrical cutting requires the use of a

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relatively expensive non-conducting fluid medium such as
isotonic glycine. If a conducting fluid such as saline is
used, the cutting current can be short-circuited away from
the work. The fluid must be isotonic to avoid intravascular
5   hemolysis.

Further, the prior procedure is incapable of
removing bladder stones, which may necessitate two operations
where a single operation would have been preferable.

Since the EUA is frequently used in the field of
10 transurethral resection, the EUA must frequently be inserted
into the urethra. Therefore, the circumferential size of the
sheath of the EUA is limited by the elastic extension of the
urethra which is typically about 30 mm (or about 28 French).
Surgeons, however, prefer to use sheaths of smaller size,
15 such as 24 or 25 French, to avoid the occurrence of stric-
tures or contractions of the urethra following excessive
endoscopic dilation.

Endoscopic ultrasonic tissue removal and aspiration
avoids these disadvantages. Ultrasonic tissue removal has
20 been employed in the past for dissection and removal of
biological tissue. However, no ultrasonic instrument has
been available to remove highly compliant tissues through a
narrow orifice, for example in transurethral prostate
resection. The prior art has two principal failings. First,
25 there was no long, slender probe capable of sustaining
ultrasonic vibrations at the high tip velocities that are
necessary for removal of such tissues. Second, the art has
not realized that the most efficient tissue removal is by
ultrasonic vibrations causing cavitation of the fluid within
30 the cells. Such vibrations should preferably be in the 10-20
kHz range, although other frequencies may be used. The term
"ultrasonic" will be employed herein to refer to all the
frequencies of interest, including some frequencies in the
audible range.

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In one early development, Von Ardenne and Grossman reported in 1960 on the use of ultrasonic vibration to assist in inserting small-gauge wire probes and hollow needles into the skin. They mention constructing an ultrasonically vibrating needle connected to a syringe which is adapted to inject or withdraw fluid or other material from adjacent the tip of the needle. They employ a velocity transformer of the exponential type and operate at a frequency of about 25 kHz with a tip excursion of about 10- 100 microns.

Also in 1960, Watkins et al. reported the use of an ultrasonic chisel to fracture and remove calcium deposits from cardiac valves. The authors state that their technique is unusable on soft, flexible tissues since the belief at the time was that such tissues are relatively undisturbed by ultrasonic vibration. Their apparatus operates at about 26.5 kHz with a tip excursion of about 38 microns.

Ultrasonic energy has also been employed to cavitate a liquid medium to burst and destroy suspended microorganisms for either sterilization or extraction of the protoplasm. This technique typically employs a solid round metal horn immersed in the liquid medium and vibrating at perhaps 20 kHz with a stroke of about 20-40 microns. It operates by cavitating the water around the cells, rather than the intracellular water.

Prior patents have disclosed surgical instruments in which ultrasonically vibrating tools remove unwanted biological material while providing irrigation of the work area and aspiration of fluids and removed material. See, for example, U.S. Patent 2,874,470 to Richards, U.S. Patent 3,526,219 to Balamuth, U.S. Patent 3,589,363 to Banko and Kelman, and U.S. Patent 4,063,557 to Wuchinich et al. The Richards device is a dental instrument which operates above the audible range, preferably at about 25 kHz, with an amplitude of about 10 microns. In the Balamuth '219 device,

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a sharp-edged tool vibrating at about 25 kHz directly
contacts tissue to "chop" it. In the Banko and Kelman '363
device, a thin-walled tubular tip which vibrates with an
amplitude of about 50-70 microns breaks apart and removes
5   relatively hard biological material such as cataract material
in the lens of the human eye. The Wuchinich et al. '557
patent discloses a device for removing compliant tissues such
as neurological neoplasms, employing a magnetostrictive
transducer which vibrates at about 25 kHz with a stroke of
10   about 25 microns. A stepped and tapered mechanical
transformer increases the stroke to about 125-400 microns.
           None of these devices has been capable of providing
sufficient tip velocity and a long and narrow enough probe to
perform endoscopic surgery. The greatest insertable distance
15   available with prior ultrasonic surgical instruments has been
about 7-8 cm. More particularly, prior devices have been
unable to exert sufficient sound pressure on compliant cells
in a biological tissue structure such as a glandular tumor to
produce cavitation in the intracellular fluids of the cells,
20   or to disintegrate them in any fashion.

SUMMARY OF THE INVENTION

           The prior art devices being ineffective, it was
desired to improve the speed and efficiency of tissue
25   removal, and provide a vibrating probe longer and faster than
was previously available for endoscopic surgery.
           Experiments by the inventors have shown that the
effectiveness of ultrasonic vibration on biological tissues
is related to the water content of the tissue. Tissues that
30   have been allowed to dehydrate are much less amenable to
attack and removal by vibration than those that are fresh or
have been kept moist. It has also been seen that the walls
of blood vessels or the connective tissue overlying muscles
and brain tumors are not affected by an ultrasonically

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vibrating tool nearly as much as soft, fleshy specimens such
as neoplasms, or muscle tissue. Since the intracellular
water content of the unaffected tissues is much lower than
that of the tissues that are affected to a greater extent,
this "tissue-differential" or "tissue-selective" effect seems
to be related to the water content of tissue.

The present inventors conceived that the tissue-
differential effect could give ultrasonic aspiration a unique
advantage in endoscopic surgery, since the undesired tissue
could be removed without risking injury to other structures
under difficult conditions of visibility and access to the
operating site.

Because of the relationship between tissue removal
and water content, the inventors hypothesized that the
physical mechanism causing the parting of tissue was the
destructive effect of intracellular cavitation, i.e., the
formation, due to rapidly varying pressure, of microscopic
vapor bubbles in the intracellular fluids. For a given level
of pressure in a fluid, the degree of cavitation is
determined by a number of the fluid's physical properties,
for example temperature, surface tension, viscosity, vapor
pressure and density. Very important is the dependence of
cavitation upon (1) the applied pressure, and (2) the
frequency at which the applied pressure oscillates. Studies
have suggested that the intensity of cavitation in water
increases as the frequency of vibration is lowered. This
hypothesis was tested by setting up two transducer tips
having exactly the same size but providing different
frequencies of pressure oscillation. Since the pressure
produced by oscillating motion is proportional to the
velocity of this motion, both tips were operated with the
same velocity at the point of tissue contact. One tip
vibrated at 40 kHz, while the other vibrated at 20 kHz. On
the same specimen, the use of 20 kHz vibration approximately

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doubled the rate of tissue removal -- confirming a relation
to cavitation, and disproving any suggestion that tissue
fragmentation could be enhanced only by increasing
vibrational amplitude or acceleration. Similarly, it was
5   found that the cavitation rate again doubles when the
frequency is further lowered to 10 kHz. Below a threshold of
10 kHz, the rate remains constant.

There is also a pressure threshold, below which it
is not possible to cavitate a given fluid. This threshold
10   also decreases with frequency down to about 10 kHz, below
which the pressure threshold does not decrease further.

For these reasons, the frequency regime preferably
embraced by this invention extends from 10 kHz to 20 kHz, and
thus encompasses part of the aural spectrum, although of
15   course lower or higher frequencies could be used. It was
previously assumed that the use of audible frequencies would
be irritating and dangerous to the surgeon and that the
frequency should be restricted to the inaudible range above
18 kHz. Longer wavelengths were also discouraged because a
20. half-wavelength transducer at 20 kHz would be about 5 inches
long, approximately the maximum length for convenient hand-
held use.

However, the present inventors have found that in
an endoscopic device different considerations apply than
25   those previously known to the art. In endoscopic surgery
most of the vibrating components are placed within a natural
body orifice, such as the urethra, so that the radiation of
aural sound is greatly damped by the intervening body
tissues. In some percutaneous applications, such as
30   arthroscopic surgery, while only part of the instrument may
be placed within tissue, the sound radiated from the exposed
parts is minimal and can be effectively limited if desired by
the use of absorbing sheaths and enclosures over the
transducer and a portion of the tip.

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Even with the use of the most advantageous
frequencies, the maximum possible tip velocity should also be
employed to further enhance pressure and hence cavitation.
Since pressure is related to the velocity of the transducer
5   by the conventional formula $P = ZV$, where Z is the acoustic
impedance of the fluid, the relationship between cavitation
and pressure translates into a direct dependence of
cavitation upon velocity. Cavitation is believed to be
relatively independent of both the acceleration and the
10   amplitude of vibration.

Velocity cannot be increased without limit,
however, since there is a definite physical limit to the
velocity at which probes or tips made out of known materials
can be safely vibrated. The mechanical stress at a given
15   point within a vibrating tip is directly related to the tip
velocity at that point. Increasing the tip velocity
correspondingly increases the stress within the tip until it
exceeds the strength of the crystalline bonds within the tip
material and the tip fractures. Special designs can be
20   developed to permit great tip velocities for a given maximum
stress, but prior art designs have invariably increased the
cross-sectional size of the tip and have been difficult to
fabricate. Therefore, in addition to lowering the frequency
of vibration, an important object of the invention is also to
25   increase the cavitation rate by providing improved apparatus
to enhance the available tip velocity without exceeding the
maximum permissible stress on the tip material.

For a regular structure, such as a tube with
constant cross-section, the tip velocity at a given point is
30   related to stress according to the equation $s = pcv$, where v
is the velocity (distance per unit time), p is the density of
the material of which the tip is made (mass per unit volume),
c is the velocity with which extensional sound waves travel
in the tip (distance per unit time) and s is the stress in

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the tip (force per unit area). For titanium, which is
capable of bearing the greatest stress of any commonly
available material, the above relation means that maximum
permissible velocity is approximately 1270 centimeters per
5   second. However, it is known that effective removal of living
tissue preferably employs velocities of at least about 2540
centimeters per second.

        To improve tissue removal, greater tip velocity may
be obtained by use of a velocity transformer having non-
10 uniform cross-section. The equation above applies only to
uniform structures, such as tubes having a constant cross-
sectional area. If the tube is made non-uniform, the
equation is modified by a shape factor M, sometimes called a
figure of merit:

15                          $$s = \frac{pcv}{M}$$

Depending upon how the alteration is made, the shape factor
either increases or decreases the available tip velocity for
a given maximum stress. Of interest here is finding a tip
design whose shape factor is greater than one.
20
        It is clear from the modified equation that
for a given maximum allowable stress, the tip velocity may be
increased over that obtainable in a uniform tube by a factor
of M.

25   There are a variety of tip designs in which the
tip's cross-sectional area varies with respect to its length
to provide a value of M that is substantially greater than
one. For example, exponential tips whose cross-sectional area
varies along its length as

                        $$Area = A_o e^{-aL}$$
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where e is the natural base, Ao and a are constants and L is
the distance from the point in question to the end of the
tip, can theoretically provide a shape factor equal to e or
2.7. However, to obtain this value of M requires that the
tip begin and end with drastically different diameters. A
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tissue removal device employing an exponential design with a
shape factor of 2, which could safely produce a tip velocity
of 25.4 m/sec, would begin with a diameter roughly five times
that of the surgical end. In an endoscopic device that must

5   extend several inches into a narrow body orifice, an
exponential design is impractical. If built to accommodate
the limitations of human anatomy, its tip would be too small
to remove tissue at a practical rate.

It has been found that the most space-efficient

10 design for increasing the value of M from 1 to approximately
2 employs the use of a constant-stress velocity transformer
coupled to a constant-diameter velocity transformer. In a
uniform tube executing extensional vibration, the stress
obeys the relation

15          $$s = \sin \pi x/L$$

where x is the distance to the point in question from one end
of the tube, and L is the total length of the tube. It can
be seen from this relation that the stress is maximum when
x=L/2. Thus it would be desirable to provide at the working

20 end of a surgical probe having length L/2 a further section
with varying cross-sectional area, so that for values of x
greater than L/2 the stress will remain constant at the
maximum permissible value.

Also, such a design would produce the greatest

25 possible extension for a given maximum stress. Since Hooke's
law dictates that the extension of each portion of the
transformer is proportional to stress, and since the stress
is constant, the extension linearly increases along the tip
length beyond its midpoint.

30   It will be shown below that such a tip, in the
region designed for constant stress, has a cross-sectional
area obeying the relation

$$Area = Be^{-by2}$$

where B and b are constants and y is the distance from a

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given point to the end of the tip. This mathematical
function is known as the Gaussian function, after the
mathematician Gauss who studied its properties.
Consequently, the constant-stress tip will be referred to as
5   a Gaussian resonator. Gaussian resonators provide a
significant improvement over any alternative design since
they can be made with diameters that can be accommodated by
the human anatomy with a sufficiently large tissue contact
area and aspiration port to permit efficacious tissue
10   removal, and can exhibit a shape factor of 2, making it
possible to practically attain a velocity of 25.4 meters per
second in an endoscopic or percutaneous device. Further, the
Gaussian design does not require a wide disparity between the
two end diameters.
15   The cross-sectional area progressively
decreases along the length of the resonator so as to keep the
stress constant, but it need not do so very close to the
tissue- contacting end of the tip. Since there is no load on
this point, the stress is zero, so the very end of the tip
20   need not be designed to sustain the same stress but rather
may be contoured and rounded to gradually lower the stress to
a value of zero.
            The mathematical basis for providing a Gaussian
resonator in the EUA is as follows: well-established
25   acoustical principles establish the parameters that affect
the maximum velocity available from slender bars undergoing
simple extensional vibration. For a uniform bar, with both
ends free, the maximum obtainable velocity is directly
related to the maximum stress that the material of which the
30   bar is made can safely withstand:

$$V_{max} = \frac{S_{max}}{pc} \qquad (1)$$

where V_{max} is the velocity (distance per unit time), S_{max} is
the safe stress limit (force per unit area), p is the
35   material density (mass per unit volume), and c is the

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velocity with which extensional waves travel in the material
(distance per unit time). Since metals are the only
practical materials capable of sustaining the high-level
acoustic vibration of interest, and since c is approximately

5   the same for all these metals, to obtain the largest possible
value of V_{max}, a material should be selected that has the
highest possible strength-to-weight ratio (S_{max}/p). This
material has been well established to be aircraft titanium.
The safe value of vibrational stress has been determined by

10 experimentation to be one-third the value of the yield stress
(the stress at which the metal begins to irreversibly
deform). When V_{max} is computed using the appropriate values
of S_{max}, p and c, it is found that

$$V_{max} = 1219 \text{ cm/sec.} \tag{2}$$

15 for a uniform bar of aircraft titanium.

However, this velocity provides only a small degree
of soft tissue dissection, even when the frequency of
vibration is lowered to enhance cavitation of intracellular
water. A value approximately twice that given by Eq. 2 is

20 desirable to effectively disintegrate such tissue.
Consequently a velocity transformer is desirable that
approximately doubles the value of V_{max} without increasing
the maximum stress above S_{max}. It is also desirable, in an
endoscopic device, for this velocity transformation to be

25 accomplished within a narrow circular channel preferably
about 8 millimeters in diameter, of which about 4 millimeters
constitutes a circular aspiration bore. It is therefore
important that the velocity be increased with a minimum
change in cross-sectional area so that the entire resonator

30 can be placed within the endoscope over a length of at least
about 17-19 centimeters.

FIG. 1 shows a hypothetical velocity transformer
consisting of a uniform section one-quarter wavelength long,
followed by an integral second section of length L. Fig. 2

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illustrates various possible stress distributions in this bar
for different hypothetical cross-sectional variations of the
second section. The velocity at any point to the right of the
uniform section can be written as

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$$v(x) = [-2 \pi f / E] \int^x_o s(x) dx, \qquad (3)$$

where $s(x=o)=S_{max}$, $s(x=L)=0$, f is the frequency of vibration
(cycles per unit of time), and E is the elastic constant or
Young's Modulus (force per unit area). Thus, the velocity
distribution along the section can be computed directly from

10 these stress distributions. The velocity at any point is
proportional to the area under the stress curves to that
point. FIG. 3 illustrates these corresponding velocity
distributions. Curve 1, although it produces the largest end
velocity, exceeds S_{max} and therefore is not a practical

15 choice. Curves 2 and 3 produce safe stress distributions,
but do not result in the maximum attainable end velocity.
The areas under these curves in FIG. 2 are less than the
areas under curves 1 and 4.

    Curve 4 alone increases the velocity most rapidly

20 while maintaining a safe operating stress. Curve 4
represents a constant stress level in the section, except at
the terminus, which is free and therefore is not subject to
any force.

    It remains to be determined how to contour the

25 second section so as to produce this optimum stress
distribution. The velocity distribution in an extensionally
vibrating slender bar is related to the stress and cross-
sectional area as

$$[2\pi f]p \cdot A(x)v(x) = A(x) \cdot \frac{\partial s(x)}{\partial x} + s(x) \cdot \frac{\partial A(x)}{\partial x} \qquad (4)$$

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Since $\qquad s(x) = S_{max}$, for $0 \le x \le L$, $\qquad\qquad$ (5)

and since $\qquad \frac{\partial s(x)}{\partial x} = 0$ $\qquad\qquad\qquad$ (6)

then v(x) and s(x) are related by Eq. 3 with $s(x) = S_{max}$,

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which results in
$$v(x) = \frac{-2\pi f}{E} \cdot S_{max} x \qquad (7)$$

Substituting Eqs. 5, 6 and 7 in Eq. 4, there results the condition:
$$\frac{1}{A(x)} \frac{\partial A(x)}{\partial x} = -[2\pi f /c]^2 \cdot x \qquad (8)$$

which, when integrated between $A(x=o) = A_o$ and $A(x)$, and between $x=o$ and $x=x$, yields
$$A(x) = A_o e^{(-k^2 x^2 /2)}, 0 \le x \le L, \text{ where}$$
$$k^2 = [2\pi f/c]^2. \qquad (9)$$

Thus, to obtain the optimal velocity transformation, the cross-sectional area of the resonator must progressively decrease from its value at x=0 as dictated by Eq. 9, which is the Gaussian function.

There is no theoretical limit to the amount the velocity may increase so long as A(x) satisfies Eq. 9. As a practical matter, the resonator is hollow, and ultimately the wall thickness required for ever-diminishing values of A would produce a structure insufficiently strong for the rigors of medical use. However, the Gaussian resonator does exhibit a velocity transformation factor of at least 2 with an acceptable starting cross-sectional area A_o, making practical the attainment of tissue dissection with an endoscopic device.

Constant-stress amplification can also be achieved in a uniform structure such as a cylindrical tube by varying the elastic constant E, or both the elastic constant E and the density p, over the length of the structure, without varying the cross-sectional area.

An example is a system is which density is proportional to the elastic constant, that is, p = nE where n is a constant. It is found that constant stress can be obtained in such a system if E is varied according to the Gaussian function:

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$$E + E_o e^{-n}(2\,\pi\,fx)2/2, \qquad (10)$$

where $E(x=0)=Eo$. Thus , the elastic constant E decreases
from the vibration input to the free end of the resonator.
Under these conditions,

$$v(x) = -2\pi\,fS_{max} \quad [s(x)/E(x)] \; dx. \quad (11)$$

Since $S(x) = S_{max}$ in a constant-stress system,

$$v(x) = 2\pi fs\; S_{max} \qquad 1/E(x) \; dx. \qquad (12)$$

Since $E(x)$ is a decreasing function, the integral in Equation
(12) increases at a faster rate than it would if $E(x)$ were a
constant function as in Equation (3) above, so greater
velocity amplification can be expected under these conditions
than in a system in which cross-sectional area is varied to
achieve constant-stress conditions.

According to one aspect of the invention, high-
frequency vibration apparatus comprises a vibration source,
for vibrating with a first amplitude, a first transformer for
amplifying the vibrations, and a second transformer for
amplifying the vibrations of the first transformer, the
second transformer being elongated and when vibrating having
a substantially constant mechanical stress level in
substantially all of its length. The second transformer may
have a cross-sectional area that varies from its input end to
its output end so as to provide such substantially constant
mechanical stress level. The cross-sectional area of the
second transformer may vary according to the Gaussian
function. Alternatively, the substantially constant stress
level may be provided without varying the cross-sectional
area by varying the elastic constant of the material of the
transformer, or both the elastic constant and density of the
material.

A further form of the invention includes a
handpiece, a vibration source for vibrating with a selected
wavelength and with a first amplitude, a first transformer
for amplifying vibrations from the vibration source, and a

second transformer for amplifying vibrations from the first
transformer, the first transformer having an input section
relatively large in cross-sectional area and coupled to the
vibration source, and also having an output section, and the
second transformer having an input end coupled to the output
section of the first transformer, and having an output end
vibrating in response to such received vibrations.

According to a further form of the invention, an
endoscopic ultrasonic aspirator comprises a hollow handpiece,
an elongated sheath having a hollow bore running from the
interior of the handpiece to a working end away from the
handpiece, a vibration source powered by alternating current,
an elongated tool coupled to the vibration source and passing
through the hollow bore of the sheath to a work site for
transmitting such vibrations, viewing means extending from
the handpiece to the work site, means for supplying fluid to
a fluid space between the tool means and the hollow bore of
the sheath, and fluid detection means for detecting the
presence of fluid in the fluid space and terminating the
supply of alternating current to stop the vibrations when
such fluid is not present.

In another form of the invention, an apparatus for
removal of unwanted biological material comprises a
handpiece; an elongated sheath extending from the handpiece
and having a hollow bore; a vibration source in the
handpiece; first and second transformers in the hollow bore
for amplifying vibrations from the source to a sufficient
velocity to disintegrate unwanted tissue, the vibration means
and the two transformers being elongated and having a
continuous hollow bore extending along a common longitudinal
axis to form (1) a first fluid passage in a space defined
between the transformers and the sheath, and (2) a second
fluid passage along the common longitudinal axis; means for
introducing fluid into one of the fluid passages to irrigate

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an operating site adjacent a working tip of the second
transformer; and means for applying suction to the other of
the fluid passages to remove such fluid and such
disintegrated unwanted tissue from the operating site.
5   According to a further aspect, the means for applying suction
includes a biopsy valve coupled to the fluid passage to which
suction is applied for selectively diverting fluid and tissue
therefrom, and trap means for receiving and filtering the
desired fluid and tissue that has been selectively diverted.
10   A further aspect of the invention is a method for
removing cellular material from a compliant tissue relatively
deep within a biological body through a narrow orifice,
comprising inserting an elongated surgical instrument into
the orifice, with a working tip located close to the material
15   to be removed, and vibrating the working tip so as to
disintegrate such material. A further method provides
removal of cellular material from a compliant issue at an
operating site at least about 8 cm deep within a biological
body through a narrow orifice, preferably no more than about
20   29 mm in circumference, comprising inserting a narrow
elongated surgical instrument at least about 8 cm deep into
the body through the orifice with a working tip of the
instrument being located close to the material to be removed,
and vibrating the working tip longitudinally so as to produce
25   pressure waves to disintegrate the material. The vibration
of the working tip advantageously cavitates the intracellular
fluids in such material to destroy its cells. Vibration is
preferably at about 10 to 20 kHz, with a longitudinal stroke
of at least about 350 microns, Preferably at least about 700
30   microns; and with a maximum velocity of at least about 1,000
cm per second, preferably at least about 2,000 cm per second.
           A further form of the invention is a method of
removing cellular material from a compliant tissue at an
operating site deep within a biological body through a narrow
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orifice, including providing a surgical instrument having an
elongated sheath at least about 8 cm in length and no more
than about 29 mm in circumference, the sheath having a hollow
bore; locating an elongated probe within the hollow bore, the
5   probe having a working end projecting beyond the end of the
sheath and a hollow bore therethrough, thereby forming a
first fluid passage in the space between the probe and the
sheath, and a second fluid passage within the probe;
inserting the sheath into the body orifice with the working
10   end of the probe close to the material to be removed;
introducing a fluid into one of the fluid passages to
irrigate the operating site; vibrating the probe
longitudinally so as to produce pressure waves sufficient to
disintegrate the cells of the material to be removed; and
15   applying suction to the other of the fluid passages to
withdraw the fluid and the matter to be removed from the
operating site.

        Employing the invention in transurethral resection
of the prostate achieves many benefits such as (1) the
20   tissue-differential effect, (2) a thermal cauterization and
an absence of necrosis, which should greatly accelerate
healing, (3) retrograde motion of the instrument permitting
direct visualization of the procedure, (4) capability of
removing bladder stones or the like, and (5) reducing the
25   duration (and hence increasing the safety) of the procedure
by increasing the tissue removal rate and permitting
continuous operation.

        The tissue selectivity of the endoscopic ultrasonic
procedure reduces the risk of piercing the prostate capsule
30   or bladder unless the instrument is forced by the operator.
Any obstructions such as blood vessels are easily felt by the
operator in that the handpiece is directly mechanically
connected with the working tip, leading to an inherently
safer procedure that can be used with less training than the

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prior procedure.

     The ultrasonic procedure also causes minimal microscopic tissue distortion, allowing more precise histological diagnosis. The aspirated tissue can be diverted quickly to a biopsy trap of the system and removed for analysis. A further advantage is the elimination of electrical currents passing through the patient's body, avoiding the risk of shock effects, burns, or the obturator nerve reflex.

     Employing continuous aspiration of the debris and water shortens the operative time to as little as one-half hour. This results in diminished operative bleeding, as well as generally decreasing operative risk to the patient. Further reduction of bleeding results from the cauterization effect of the friction of the moving tip on adjacent tissue.

     Also, using ultrasonic tissue removal combined with continuous irrigation and aspiration permits retrograde cutting, giving the surgeon better visibility of what lies in the path of the cutting edge. Since the pieces of removed tissue are small they are easily aspirated, permitting the surgeon to take one continuous cut with good visibility for any length of prostate tissue to be removed.

     The present invention also relates to an endoscopic ultrasonic aspirator with a tip having a reduced circumference which also provides the surgeon using the aspirator with an increased view of the operating site.

     The invention further relates to an improvement of an endoscopic ultrasonic aspirator of the type which includes a resonator having a vibrating tip for removal of biological material, means for delivering fluid to the tip, means for removing the fluid and removed biological material, and means for viewing the operation of the vibrating tip. This improvement comprises open channel means connected to the resonator tip to facilitate viewing of the tip during use and

means for supporting the open channel means and forming a
passage to assist in the proper operation of the aspirator as
to the removal of the fluid and removed biological material.
If desired, the entire length of the resonator can be

5   configured and dimensioned in the form of open channel means
so that the viewing means can be partially received, held and
supported by the open channel means, thus minimizing the size
of the aspirator. Preferably, the open channel support means
is a resilient plug and the channel means has a U or V shaped

10   cross section.

        According to a preferred embodiment of the present
invention, the tubular ultrasonic tip of the aspirator is cut
open along its length. The telescope is then suspended
within the cut-out portion of the tip. The end of the

15   ultrasonic tip thus has a U shape in cross-section with the
telescope being suspended within the U. As a result, the
under-surface of the telescope partially closes off the
opening of the U shaped tip so that a cross-section of the
opening at the tip near its operational end has a crescent

20   shape.

        Because the telescope is partially inserted into
the end of the ultrasonic tip, the overall circumference of
the end of the aspirator of the present invention is less
than that of the end of an aspirator in which the ultrasonic

25   tip is circular in cross-section where the telescope is
placed adjacent to the ultrasonic tip. Additionally, since
the upper portion of the ultrasonic tip adjacent to the tele-
scope has been removed, the surgeon's view of the operating
site is not obstructed by the ultrasonic tip. To ensure that

30   the relative positions of the telescope and the ultrasonic
tip do not change, a plug may be inserted between the
telescope and the U shaped tip. The ultrasonic tip and plug
are then mounted within a sheath or lower lumen which is
attached to the upper lumen in which the telescope is

35   mounted.

        Other objects, features, and advantages of the

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invention will be seen in the following detailed description
of preferred embodiments, with reference to the accompanying
drawings.

5   BRIEF DESCRIPTION OF THE DRAWINGS
         FIG. 1 shows a hypothetical extensional resonator
for use in illustrating the background of the invention;
         FIG. 2 shows a family of curves illustrating
possible stress distributions in the resonator of FIG. 1;
10   FIG. 3 shows a family of curves illustrating
velocity distributions corresponding to the stress
distribution curves of FIG. 2;
         FIG. 4A and 4B together form a view, partly broken
away, of an endoscopic ultrasonic aspirator (EUA) according
15 to an embodiment of the invention;
         FIG. 5A is an elevational view of a resonator
assembly including a transducer and first and second velocity
transformers for use in the EUA of Figs. 4A and 4B;
         FIG. 5B is a graph showing extension and stress
20 distributions in the components of FIG. 5A;
         FIG. 5C shows an alternate resonator assembly;
         FIG. 5D shows another alternate resonator assembly;
         FIG. 6 is an end view of the EUA taken along line
6-6 in FIG. 4B;
25   FIG. 7 is a detail of FIG. 6 showing an end view of
telescope 28 of the EUA;
         FIG. 8 is a plan view of a sealing ring 112
employed in the EUA;
         FIG. 9 is an elevational view of part of an
30 alternate embodiment of the invention;
         FIGS. 10A and 10B together form a block diagram of
an ultrasonic power supply for use with the EUA;
         FIG. 11 is a cross-sectional view of the EUA taken
along line 11-11 of FIG. 4A;

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FIG. 12A shows schematically an irrigation system for use with the EUA;

FIG. 12B shows schematically an aspiration system for use with the EUA;

FIG. 13 is a schematic diagram of part of an alternate ultrasonic power supply for use with the EUA.

FIG. 14 is perspective drawing of an embodiment of the open channel endoscopic ultrasonic aspirator of the present invention;

FIG. 15 is a cross-sectional view of the embodiment of FIG. 14 taken along the line 15-15;

FIG. 16 is a cross-sectional view of the embodiment of FIG. 15 taken along the line 16-16;

FIG. 17 is a cross-sectional view of the embodiment of FIG. 15 taken along the line 17-17; and

FIG. 18 is a cross-sectional view of the embodiment of FIG. 15 taken along the line 18-18.

FIG. 19 is a view of the transformer input section of the invention;

FIG. 20 is a view taken along line 20-20 of FIG. 19;

FIG. 21 is a view of the transformer input of the invention when the telescope is inserted;

FIG. 22 is an illustration of the transformer input section with telescope inserted and which is further sealed with an elastomeric material;

FIG. 23 is a view of FIG. 22 with a portion of the elastomeric sealing material removed;

FIG. 24 is a cross sectional view similar to FIG. 15, but illustrating an alternate embodiment of the invention; and

FIGS. 25, 26 and 27 are detailed views of resonator tip modifications for the invention.

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DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIGS. 4A and 4B show an endoscopic ultrasonic
aspirator according to a preferred embodiment of the
invention. A handpiece 20 is located at what will be
referred to as the rear end of the device. A sheath 22
extends from the handpiece 20 toward what will be referred to
as the working end of the device. A stop assembly 24,
integral with the sheath 22, couples the handpiece to the
sheath. The handpiece is preferably plastic and the stop
assembly and sheath are preferably metal. The EUA also
includes a straight telescope 28 which runs horizontally from
the rear end to the working end of the EUA. A horizontal
upper lobe 26 of the handpiece 20 contains an aperture 30
through which the telescope passes to the exterior of the
handpiece. The handpiece also has a lower lobe 32 which
forms an angle A with the upper lobe 26. Angle A may
advantageously be about 20 to 45 degrees, its purpose being
to allow various components to be located within the
handpiece without interfering with the straight horizontal
line of sight occupied by the telescope.

The sheath 22 is assembled to the handpiece 20 by
means of a stop assembly 24, which is integral with the
sheath 22 at its rear end. The stop assembly 24 is generally
cylindrical and has a circular aperture in its rear side with
inward-facing threads 34. The handpiece is circular at its
forward end and has outward-facing threads 36 which are
adapted for screw-mounting in the threads 34 in stop 24. The
stop 24 has a forward portion 38 with annular faces 40 and 42
which face rearward and forward, respectively. The handpiece
is screwed into the rear aperture 30 of the stop assembly
until it comes into contact with the rear face 40. The front
face 42 of stop 24 limits the distance to which the working
end of the sheath 22 of the EUA can be inserted into a
surgical orifice.

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The telescope 28 has at its rear end an eyepiece 50
and a cable 52 for supplying electrical energy to an
electro-optical light source 54. From the eyepiece the
telescope extends forward in a straight line of sight to the
5   working end of the EUA. The design of the telescope is shown
in more detail in FIG. 7. The telescope includes a
cylindrical lens system 56 which is located adjacent the
lower portion of the cylindrical inner surface 58 of the
cylindrical telescope 28. In the crescent-shaped space
10   between the inner surface 58 and the lens system are disposed
optical fibers 60 which carry light from the light source 54
to the working end of the telescope. Other illumination
sources may be provided. In this embodiment, the outside
diameter of the telescope 28 is approximately 3-4 mm, and the
15   outside diameter of the lens system 56 is perhaps 1.7 - 2.7
mm, depending on the size of the overall telescope 28.

Disposed within the handpiece and sheath is a
resonator assembly generally designated 68. The resonator
assembly 68, which is seen more clearly in FIG. 5, includes a
20   piezoelectric transducer 70; a first velocity transformer 72
having a relatively thick curved input section 74 coupled to
the transducer for receiving vibrational energy therefrom,
and an integral narrower output section 76 extending
forwardly of the input section 74; and, integrally connected
25   to the forward end of the output section 76, a second
velocity transformer 78, which extends from the output
section 76 to the working end of the EUA and protrudes
slightly beyond the sheath 22. The transducer's length is
substantially one-half of the wavelength of the vibrations
30   employed in the device. Thus, the transducer has vibrational
antinodes (loops) at its ends and a vibrational node halfway
between its ends. The length of the curved input section 74
of the first transformer 72 is one-quarter wavelength; thus,
its point of connection with the transducer 70 is an

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antinode, and the point of connection to the output section
76 is a vibrational node. The length of the output section
76 is one-half wavelength. Thus an antinode is at the center
of this section, and a node exists where it is connected to
5   the second velocity transformer 78.

        The second transformer 78 is of the Gaussian type
described above. As seen in the schematic graph in FIG. 5,
there is little longitudinal extension and little stress in
the input section 74, because it is relatively massive and a
10   substantial amount of its vibration is flexural. Stress is
high at both ends of the output section of the first
transformer, but is zero at its center point, which is a
vibrational antinode or loop with greatest longitudinal
extension. The stress in the output section 76 is at the
15   maximum permissible level for the material and design
employed, in other words S_{max}, as defined above. The
Gaussian resonator 78 exhibits constant stress at this same
level S_{max} throughout most of its length, almost to the tip
80 at its working end. The stress near the tip 80 is
20   substantially zero, since there is ordinarily little or no
load on the tip.

        As seen in FIG. 6, the second transformer 78 and
also the output section 76 are not round. Rather, flats are
formed in the top and bottom of these members to provide
25   ample water passages without substantially changing their
vibratory characteristics. The central bore 110, however, is
substantially circular, with an inside diameter of perhaps
4.33 mm (13 French).

        The working end 80 need not lie in a vertical plane
30   as shown, but may be angled or otherwise shaped if desired in
a particular application.

        The combined length of the output section 76 and
the second transformer 78 is advantageously about 19 cm. If
desired, it could be lengthened by any integral multiple of

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one-half wavelength, which at about 20 kHz is about 13 cm.

A piezoelectric transducer such as is used herein typically has a maximum vibration amplitude of about 23 microns. At the frequencies of interest, tip vibration at
5   the necessary velocity entails an amplitude of about 350 microns. The resonator assembly 68 provides this 15-fold increase in vibration amplitude.

A groove 90 is formed in the top of the transformer input section 74 and is sized to accommodate the telescope.
10   The groove 90 permits the telescope to be located closely parallel to the transformer sections 76 and 78 within the forward end of the sheath, without interfering with the input section 74, to achieve a compact and narrow sheath.

The letter R in FIG. 5A refers to the radius of
15   curvature of the curved input section 74. This radius must be small enough so that the handpiece is curved far enough below the line of sight of the telescope, desirably at least about 20 degrees, to achieve a compact and easily handled unit. A radius R of about 5 cm advantageously gives an angle
20   of about 40°. At an operating frequency of 20 kHz, 5 cm is about 0.2 times the wavelength. Preferably, the radius R should be no smaller than about 0.1 times the operating wavelength to avoid excessive energy losses. The radius should also be less than about 0.5 times the wavelength in
25   order to give a usable angle of offset of about 20° over the length of the input section 74, which is about 6 cm. The curvature of the input section is not necessarily circular; thus, the radius R as defined herein is an approximation.

FIGS. 5C and 5D show alternate resonator assemblies
30   68c and 68d. In FIG. 5C, a first transformer 72 is coupled to a transducer 70. As in the previous embodiment, the first transformer is a half-wave stepped transformer. Coupled to the working end of the first transformer is a second transformer 78c, which has constant cross-sectional area.

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velocity amplification is obtained by increasing the elastic
constant of the material in the second transformer from its
point of connection to the first transformer, to its tip 80c.
Optionally, the density of the material of the first

5   transformer may be decreased as a function of distance from
the first transformer to the tip.

In the embodiment of FIG. 5D, the same second
transformer 78c as just described is employed. However, in
this embodiment the first transformer 72d, which is curved as

10   in the previous embodiments, is not a stepped transformer.
Rather, velocity amplification in the first transformer is
obtained by increasing the elasticity of the material of the
first transformer and optionally decreasing the density of
the material, as a function of distance from the transducer.

15   As seen in FIG. 5D the transducer 70 and the first
transformer are not necessarily required to have the same
cross-sectional area at their coupling for sufficient energy
transfer to be obtained.

Because of the curvature of the section 74, the

20   transformer sections 74, 76, 78 may undergo a certain small
amount of transverse, flexural vibrations. However, any
transverse components of vibration in the sections 76 and 78
are damped by the presence of irrigation fluid in the
surrounding space 98 within the sheath.

25   Irrigation fluid is supplied through a hose 92, and
is controlled by a valve 94. The irrigation fluid flows
through a radial bore 96 in the outer portion of the front
section 38 of the stop assembly 24. It then passes into the
spaces 98 that surround the resonators 76 and 78 within the

30   sheath. As indicated generally in FIG. 6, the sheath has a
generally ovoid cross-section. Its circumference should
preferably be approximately 25mm, about the same as the
circumference of a circular instrument 8mm in diameter, such
dimension being known in the field as 24 French. If

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necessary a circumference of about 29 mm, corresponding to 28 French, may be usable. With 28 French or larger instruments, there is a risk of injury to a narrow orifice such as the urethra. The telescope 28 is disposed in the narrower part of the ovoid sheath 22. It is enclosed by epoxy material or the like running along the inside of the sheath to form a partition 100, which forms a watertight compartment for the telescope.

Irrigation fluid flows toward the working end of the EUA through the space 98 from the vicinity of the stop 24, damping any transverse vibrations of the transformer sections 76 and 78, as well as irrigating an operating site adjacent the tip 80. Auxiliary fluid passages may also be provided. Fluid is prevented from flowing into the handpiece by a sealing ring 112 shown in FIG. 8. The ring is generally O-shaped, but has a smaller aperture formed in its upper portion to accommodate the telescope. The sealing ring 112 seals the annular space surrounding the input transformer section 74 within the handpiece, and provides the hole 114 for water-tight passage of the telescope.

Additional sealing and support is provided by an O-ring 120 disposed about the transducer within the inner wall of the lower handpiece lobe 32. The O-ring 120 is located at the vibrational node at the center of the transducer.

The coupling between the transducer and the input section 74 may advantageously include female threads counterbored into the abutting ends of the aspiration passages 110 of the transducer and the input section, and a hollow threaded stud threaded into both of these. Such a connection allows for a smooth, fine finish of the adjacent faces of these two resonator elements, for good acoustic coupling between the faces.

Referring again to FIGS. 4A and 4B, aspiration is

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provided through a continuous concentric bore 110 extending
from the tip 80 through the second transformer 78, the first
transformer 72, and the transducer 70 to a hose 122, which is
connected to a source of suction. Other passages may be
provided as well. By these means, fluid and removed tissue
flow from the operative site and are aspirated through the
EUA away from the operating site for either disposal or
histological analysis.

The edges of the working end of the second
transformer 78 at the tip 80 are rounded, in order to provide
tissue removal by cavitation of intracellular water, as
discussed previously, without allowing indiscriminate cutting
by the tip 80, which could inadvertently injure tissues not
intended to be removed.

It is important for any transverse vibration
components of the transformer section 76 and 78 to be damped
by fluid flowing in the spaces 98, and for vibration to
terminate if there is no fluid present. For this purpose, a
fluid sensor is provided in the form of an insulated wire 124
running rearward along the telescope, and separated from the
fluid space 98 by the partition 100. The wire 124 runs
through the hole 114 in the sealing ring 112, and through the
groove 90 in the input section 74, to the interior of the
handpiece. The wire could also be set into a groove either
in the partition 100, in the bore that encloses the
telescope, or in the bore that encloses the resonators, if
desired. It may also be exposed to fluid if appropriate
insulation is provided. The wire is fine enough that it does
not interfere with the seal provided by the sealing ring 112.
The wire 124 then passes around the O-ring 120 to the
exterior of the handpiece. As explained further below, means
are provided in the high-frequency power supply circuit to
sense the capacitance between this wire 124 and the second
transformer 78, which is grounded. If the capacitance

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increases, which indicates the absence of water, then the
vibration of the transducer 70 is inhibited to prevent
excessive transverse vibrations and possible damage to the
resonator components.

5   FIG. 9 shows elements of an alternate embodiment of
the invention. In this embodiment, there is no partition
between the telescope 28a and the irrigation-fluid-
containing space that encloses the resonators 76a, 78a. To
support the telescope, a quantity 82 of biologically inert

10   silicone rubber adhesive or the like is placed between the
telescope and the junction of the resonators 76a and 78a. It
is important to employ a flexible adhesive to allow some
relative motion, even though this junction is a vibrational
node, since each point on each resonator is subject to a

15   small degree of radial vibration, which is inherent in a body
undergoing extensional vibration. As each incremental
section of a resonator is compressed it instantaneously
bulges slightly. Thus, each point on each velocity
transformer constantly undergoes a slight radial expansion

20   and contraction. These radial vibrations should be isolated
from the telescope. However, there cannot be more than about
250 - 500 microns of separation between the telescope and the
resonators because of the severe size limitation on the
sheath. This need for proximity, in view of the further need

25   for vibrational isolation, is resolved by connecting the
elements with a flexible adhesive.

           The ultrasonic generator and related circuitry for
powering and controlling the ultrasonic transducer 70 are
shown in FIGS. 10A and 10B.

30   The transducer 70 includes an elongated toroidal
piezoelectric crystal 71 that is driven by a cylindrical
high-voltage electrode 84 and an annular ground electrode 86.
(See also FIGS. 4A and 11.) The ground electrode 86 is
electrically connected to a conductive lining 116. The

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lining 116 runs the length of the transducer 70, lining the
aspiration passage 110, and is electrically coupled to the
velocity transformers. The transducer is insulated by
cylindrical insulators 88a, 88b, 88c located at the ends of
5   the transducer and between the electrodes 84 and 86.

The piezoelectric transducer and tip are driven by
the generator through a two-conductor coaxial cable 130. It
is energized by an AC signal whose magnitude and frequency
are controlled by a DC-to-AC inverter 132. This inverter
10 converts an input DC voltage to an alternating current signal
having a frequency controlled by an AC signal supplied to its
frequency control input 134 and a magnitude controlled by a
DC voltage level supplied to the inverter at its magnitude
control input 136. The frequency provided at the input 134
15 is the frequency at which the transducer is caused to
vibrate. The DC voltage supplied at the input 136 is that
required to maintain a selected amplitude of vibration at the
frequency of vibration.

The exciting frequency and voltage are derived from
20 a feedback signal obtained by adding two signals that are
proportional to the voltage and current input to the
transducer. In FIG. 10, C_1 and C_2 form a capacitive voltage
divider which produces a voltage across C_2 that is directly
proportional to and in phase with the transducer voltage.
25 The voltage across C_3 is proportional to the transducer
current, but shifted in phase by 90 degrees. The voltage
between the wiper of potentiometer R_1 and ground, which
constitutes the sum of these two potentials, is the feedback
signal. When R_1 is properly set, the feedback signal is very
30 low at all excitation frequencies except at the resonant
frequency of the transducer, since at resonance the
transducer voltage and current are 90 degrees out of phase.

At resonance, when the feedback signal is present,
its magnitude is proportional to the amplitude of vibration

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and its phase exactly equals that of the inverter output
signal.

The inductance L reactively cancels the
transducer's static capacitance; that is, the capacitance of
the cable 130 and the net capacitance of the voltage divider
C_1, C_2. This capacitance is advantageously neutralized so
that the voltage at the wiper of R_1 will be proportional to
the vibration amplitude and will be very small at frequencies
other than resonance.

The feedback signal is fed to two control loops:
one for establishing the correct frequency and the other for
establishing the desired vibration amplitude. When the
aspirator is de-energized there is of course no feedback
signal, and some means of starting vibration has to be
provided. A predetermined starting frequency is provided by
a voltage-controlled oscillator 140. In the absence of any
feedback, this oscillator runs at a frequency adjusted by
variable resistor R_3 in the general range of the expected
transducer resonance. Since, in general, this initial
exciting frequency is not the resonant frequency, a
substantial feedback signal will not be produced. However,
acoustic resonators do exhibit some greatly diminished level
of vibration at frequencies within about five percent of
their actual resonance. Therefore, a small, but detectable,
feedback signal is produced.

In the frequency control loop, the feedback signal
enters a very sensitive phase comparator 142 which produces a
DC voltage proportional to the difference between the phase
of the feedback signal and the phase of the output of the
voltage-controlled oscillator. The frequency of the feedback
signal is the same as that of the oscillator, but the phase
is not the same because the frequency is not yet at the
resonant frequency of the transducer. The output from the
phase comparator is greatly amplified by a phase error

amplifier 144 and then passed through a limiter 146 which
places upper and lower bounds upon the amplifier's output.
This amplified signal, subject to the bounds of the limiter,
is then supplied to a steering input 148 of the voltage-
controlled oscillator 140, and modifies its output frequency
until the phase difference between the feedback signal and
the output signal of the VCO is minimized. The VCO frequency
that produces this result is the actual resonant frequency of
the transducer.

10   The result of limiting the range of the steering
voltage applied to the oscillator at input 148 is to limit
the extent to which the frequency can be shifted. In
general, a complex acoustic resonator, such as transducer 70,
has more than one extensional resonance, at only one of which
15 the desired performance is obtained. Excitation at other
resonant frequencies would result in much lower vibration
levels and very poor tissue dissection. Because the
vibration levels are much lower at these parasitic resonances
and constitute a lower overall energy of vibration, if
20 precautions were not taken, the system would naturally tend
to operate at frequencies where it did less work. The
limiter 146 prevents the oscillator from being driven to
frequencies that lie outside a predetermined band which
brackets the intended resonance.

25   In the amplitude control loop, the feedback signal
is fed to a rectifier 150 which produces a DC voltage
proportional to the magnitude of the feedback signal. A
low-pass filter 152 is provided to eliminate any AC
components and extract only the direct current component.
30 This signal is then subtracted by a summer 154 from a
preselected DC voltage. The difference between these two
voltages is greatly amplified by an amplitude error amplifier
156 and is input to the main power supply 160 to control its
DC output voltage. This DC output voltage is the source of

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power to the inverter 132. It is proportional to the
magnitude of the inverter's AC output signal, which, in turn,
is proportional to the amplitude of vibration of the
transducer 70. This amplitude control loop maintains the
5   amplitude of vibration desired by the operator regardless of
the power drawn from the inverter 132 by the transducer 70,
thereby providing uniform performance in the presence of
compliant as well as resistant tissue. Since the power
available from the inverter is not limitless, internal
10   circuitry is provided in this component to safely limit the
maximum power consumption by the transducer, and thus
preclude unsafe power demands through intentional or
unintentional abuse. If the power limit of the inverter is
reached, the output vibration amplitude is automatically
15   reduced. The amplitude is reestablished at the control
setting once the excessive power requirement has been
removed.

        Also seen in FIG. 10A is a capacitance sensor 162
which measures the capacitance between the capacitance probe
20   124 and ground. When this capacitance increases
substantially, indicating the absence of water surrounding
the velocity transformers 72 and 78, the capacitance sensor
162 sets the input level at an input 138 of the inverter 132
to a level that inhibits the inverter and terminates the AC
25   output to the transducer.

        Fig. 12 illustrates an overall endoscopic
ultrasonic aspiration system. An irrigation fluid source 170
is located about 1-2 meters above the EUA. This distance
provides sufficient hydrostatic pressure to keep the bladder
30   neither distended nor collapsed.

        Aspirated fluid and tissue passes through the
aspiration hose 122 to a two-position biopsy valve 172.
Ordinarily, the debris will be directed by the valve 172
through a direct hose 174 toward the source of suction.

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However, when the surgeon sees suspected tissue of which a
biopsy would be desirable, the valve 172 can be thrown to
direct the debris to a biopsy trap 176. The biopsy trap is a
watertight vessel having a transverse screen 178 through
5   which the aspirated debris must pass. The desired tissue can
be rapidly collected on the screen and taken away for
histological analysis. The biopsy trap should be relatively
close to the EUA, for example about 0.3 to 0.5 meter.
Because it is close, the hose 122 can clear very rapidly so
10   that the biopsy material can be collected without unnecessary
delay after the suspect tissue is spotted. The trap can also
be kept sterile so that samples can be collected without
contaminating either the sample itself or the surgeon's
gloves.
15   The aspirated debris then passes through a line 179
to the main aspiration trap 180. The trap 180 is a closed
vessel having an inlet 182 surrounded by a sock- shaped
screen 184, which filters the debris. After filtration,
tissue can be removed for medical examination in bulk. The
20   trap has an outlet 186 away from the screen 184.
            The screens 178 and 184 are not particularly fine.
Their openings may advantageously be about 1 mm square so as
to pass blood clots, etc., without clogging. On the other
hand, the screen gauge is selected to trap pieces of tissue
25   whose size is about the same as the inside diameter of the
working tip 80, which is about the dimension of the tissue
that is cored out of the organ being resected.
            After filtration, the debris passes through a line
188 to a venting valve 190. The valve 190 has a check valve
30   192, which opens and passes the pressure on the line 188 to a
vacuum switch 194 if the pressure on the line 188 falls to a
predetermined low level, which would indicate that the system
is clogged. If the vacuum switch 194 opens, a solenoid 196
opens, and this opens a vent line 198, which vents the

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aspiration pressure to the atmosphere.

Overall control of aspiration pressure is provided by a main valve 200 operated by a solenoid 202.

Pumping is provided by a peristaltic pump 210. Waste aspiration fluid is received in a collecting vessel 220.

Fig. 13 shows elements of an alternate generator for driving the EUA in electro-cauterization of tissue. A double-pole, two-position switch 230 is provided for selecting the source of the signal to be applied to the transducer cable 130. In one position the switch selects the transducer drive signal across capacitors C_1, C_2 in the generator system, as discussed previously with reference to FIGS. 10A and 10B. In the other position the conductor and coaxial shield of the cable 130 are tied together and connected to a radio-frequency source 232. The RF signal is advantageously a pulsed RF current with a peak amplitude of 1500 volts. The waveform is a sharply decaying damped sinusoidal waveform with a frequency of about 500 kHz. The pulse repetition rate is about 20 kHz. To complete the circuit from the RF source to ground, a grounded dispersive electrode 234 is placed in contact with the skin of the patient. The surface area of contact should be as great as possible to prevent burns and shock effects. Thus, RF provided to the tip 80 passes through the patient to ground for endoscopic tissue cauterization.

The generator advantageously has the following operator controls: on/off foot switches for vibration, aspiration, and light; continuous/pulsed ultrasonic vibration mode; vibration amplitude; and optionally a switch 230 to connect the EUA to an RF source.

Referring to FIG. 14, the operational end of the open channel endoscopic ultrasonic aspirator generally designated 310, comprises a telescope 312 and resonator 314.

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Telescope 312 is mounted within a hermetically
sealed tube or upper lumen 316. Telescope 312 includes a
cylindrical lens system (not shown) and at least one optical
fiber (not shown) which transmits light from a light source
5   to the operating site at the end of the telescope. Other
illumination sources may be used. The cylindrical lens
system allows the surgeon to view the operating site through
an eyepiece at a point far removed from the operating site.

Resonator 314 is located within another
10 hermetically sealed tube or lower lumen 318. Resonator 314
is a tube which is cut open from its working end at least to
node 332 of aspirator 310. The significance of node 332 is
discussed in detail below. Alternatively, resonator 314 may
be cut open along its entire length. As a result, the cut
15 portion of resonator 314 is in the form of a channel having a
U shape in cross-section.

When the resonator 314 and lower lumen 318 are cut
open along their entire length, the telescope 312 is
suspended partially within this opening, and an aspirator of
20 minimum size is achieved along its entire length. Casing
320, made of a rigid material, serves principally to maintain
the telescope 312 in proper position over the cut portion of
resonator 314 and lumen 318.

The opening of the operating tip of the resonator
25 314 does not affect its ultrasonic performance provided that
at least half the tip remains. Dissection rates are
unaffected since only the lower half of tip contacts tissue
in normal usage and the tissue slivers removed by ultrasonic
dissection using complete tubular tips are never the size of
30 a full bore diameter.

In one embodiment, the resonator 314 is cut only to
node 332. Thus, the operating portion of the aspirator is of
smaller size than the opposite end which contains lumen 318.
As shown in FIGS. 14-18, the tubular casing 20 surrounding
35 the telescope 312 and resonator 314 is not round but is oval
in shape to maintain the circumference of the EUA at the

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preferred minimum range. The oval casing provides
accommodation of working implements within the smallest
possible perimeter.

5   Upper lumen 316, in which telescope 312 is housed,
fits into the opening at the end of resonator 314. Lower
lumen 318, like resonator 314, is a tube which is cut open
from its working end at least to node 332 of aspirator 310.
Lower lumen 318 is fastened to upper lumen 316 by two beads
of adhesive-sealant 326, such as an epoxy, so that upper
10   lumen 316 fits into the opening of lower lumen 318 as shown
in detail in FIG. 16. Upper lumen 16 and lower lumen 318 can
be made of any semi-rigid material; however, when upper and
lower lumens 316 and 318 are made of an electrically
insulating material, upper and lower lumens 316 and 318
15   electrically isolate resonator 314 from the remainder of the
aspirator 310, the patient and the surgeon, so that an
electrocauterizing current can be safely applied to the
resonator 314.

               In order to maintain the tip of resonator 314 adja-
20   cent to and in close proximity to upper lumen 316, plug 322
is inserted into lower lumen 318 between the lower surface of
resonator 314 and the upper inner surface of lower lumen 318.
Plug 322 is crescent shaped in cross-section so that its
surfaces engage the lower surface of resonator 314 and the
25   upper inner surface of lower lumen 318, and cause upper lumen
316 to be positioned within the opening of the U shaped tip
of resonator 314 as shown in FIGS. 14 and 16. In addition to
maintaining the position of the tip of resonator 314 adjacent
to upper lumen 316, plug 322 also helps seal the cavity of
30   the aspirator 310 between the lower surface of upper lumen
316 and lower lumen 318, leaving the aspiration channel 328
between resonator 314 and upper lumen 316 as the only opening
into that cavity. As shown in FIGS 22 and 23, a further seal
346 is located at the transformer input section, and this
35   completely prevents the removed material from contacting the
remaining parts of the aspirator.

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Even without plug 322 in place, however, fluids
would enter the channel at the point of tissue dissection.
Since there is a very small clearance between the resonator
314 and upper lumen 316, flow is principally restricted to
5   the end of the tip. The hydrodynamic resistance presented to
flow below or outside of the channel is greater than the
resistance of the open channel and therefore, substantially
all flow will take place in the intended manner i.e., by
suction through lower lumen 318.

10   Plug 322 is preferably made of a material that will
yield when brought into contact with the ultrasonically
vibrating tip of resonator 314. Illustratively, plug 322 is
made of an epoxy or polyester resin, a thermoplastic or
elastomeric material. By using such yielding materials, any
15   mechanical interference between plug 322 and the ultra-
sonically vibrating tip of resonator 314 is minimized or
removed completely by physical abrasion after the tip of
resonator 314 has begun to vibrate. During operation, tissue
aspiration proceeds in the same manner as if the tip were a
20   closed tube. Furthermore, since the dissecting edge of the
tip appears as a "U" to surgeons viewing this edge through
the telescope 312, direct vision of the entire cutting
surface is possible. Such a desirable view cannot be
obtained using a closed tube aspirator tip.

25   Use of an electrocauterizing current may prove an
advantageous adjunctive procedure in endoscopic ultrasonic
surgery. In electrocauterization, a metal tip, loop or other
surgical probe is connected to source of high voltage radio
frequency current generated by a spark gap oscillator or a
30   generator that produces the same pulsating flow of electrical
current that is characteristic of such oscillators. When the
probe is brought into contact with tissue, this current flows
through the tissue from the point of contact to a large
collecting electrode placed under the patient and in direct
35   contact with the skin.

When the ultrasonic tip is effectively insulated

from the telescope and sheath, it is possible to not only
apply the electrocauterizing potential directly to the tip,
but also, if an insulated transducer is employed to vibrate
the tip, to simultaneously apply both ultrasonic vibration

5   and electrocauterization in an endoscopic instrument for the
purpose of dissecting and cauterizing at the same time, and
thereby reducing the surgical operating time.

Upper lumen 316 and lower lumen 318 are
hermetically sealed within semi-rigid tubular casing 320.

10   Due to the shape of upper and lower lumens 316 and 318 and
the way in which they are attached to one another, a pair of
irrigation fluid channels 324 are formed when upper and lower
lumens 316 and 318 are mounted within casing 320, as shown in
FIGS. 14 and 16.

15   As discussed above, resonator 314 has a U shaped
cross-section at its operational end, but, according to a
preferred embodiment, assumes a closed-off tubular shape at
node 332. A cross-sectional drawing of the aspirator at node
332 is shown in FIG. 17. At node 332 both resonator 314 and

20   lower lumen 318 are tubular in shape and aspiration channel
328 is circular in cross-section. Since resonator 314 does
not vibrate at node 332, resonator 314 can contact the inner
surface of lower lumen 318 without adversely affecting the
vibration of aspirator 314 at its operational end. However,

25   since resonator 314 vibrates throughout its length except at
node 332, the remainder of resonator 314 between node 332 and
the transducer which causes resonator 314 to vibrate, should
not contact the inner surface of lower lumen 318. Therefore,
as shown in FIGS. 15 and 18, there is a space 330 between

30   lower lumen 318 and resonator 314 in the aspirator between
node 332 and the transducer.

In operation, after the aspirator of the present
invention has been partially inserted into a patient's body
so that the operational end of the aspirator is positioned

35   adjacent to the tissue that is to be removed by the
aspirator, resonator 314 is caused to vibrate at an

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ultrasonic frequency by a transducer.   When resonator 314
vibrates at its ultrasonic frequency, vibration of the tip of
resonator 314 allows the tip to cut through tissue.   In order
to remove the cut tissue from the patient's body, irrigation
5   fluid is pumped through irrigation fluid channels 324 of the
aspirator to the operation site.   The irrigation fluid is
removed from the operation site by suction that is applied to
aspiration channel 328 of resonator 314.
        Because the end of resonator 314 near its
10   operational end has a U shape in cross-section, irrigation
fluid can enter aspirator channel 324 along the entire cut
open section of resonator 314 within lower lumen 318, thereby
reducing the amount of suction at any point along the cut
open section.   However, since the end section of lower lumen
15   328 is sealed by plug 322, leaving only the U shaped opening
of aspiration channel, suction is maintained within lower
lumen 318 so that there is sufficient suction at the
U-shaped tip of resonator 314.
        Although the most preferred resonator shape is a
20   half circle or U shape in cross section, other shapes can be
used.   For example, a V-shape or an open rectangular or
square shape having straight, angled, or rounded corners is
also acceptable.   The provision of any of these shapes for a
channel type (i.e., a base portion with two side portions and
25   an open top) member is within the scope of this invention.
Also, plug 322 would be designed to match the configuration
of the resonator tip.
        When the optimum minimal size of the aspirator is
desired, the cut resonator 314 and lower lumen 318 should
30   extend throughout the entire length of the aspirator.   This
embodiment of the invention is shown in FIGS. 19-24.   Since
telescope 312 would be located partially within resonator
314 and lower lumen 318, thus providing an arrangement for
the instrument which would be similar in cross section to
35   FIG. 16 but extending throughout the entire length of the
aspirator.   The resonator is anchored at node 332 by seal

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340. This seal which can be cast from rubber or other
elastromeric material, would also prevent fluids from
seeping in the space between resonator 314 and lower lumen
318.

5   FIGS. 19-21 show the arrangement of telescope 312
and resonator 314 in the area of the transformer input
section 342. As shown best in FIG. 20, a groove 344 is cut
in the top of the transformer input section 342 to provide
space for the telescope 312. The telescope 312 is inserted
10   in groove 344 as shown in FIG. 21. This groove 344 in
transformer input section 342 along with the open channel
shape of resonator 314 enables telescope 312 to be fitted
partially therein so as to minimize the outer diamater or
French size of the overall aspiration unit.

15   In this embodiment, the open channel resonator
requires at some point a mechanism for connecting the open
channel to a closed tube or passage for removal of
biological material and fluid from the aspirator to a waste
container, collection vessel, or trap. The transformer
20   input section 342, illustrated in FIGS. 19-23, is bent at a
predetermined angle to provide space for the telescope 312.
The resonator channel 314 and the telescope 312 also
separate at this point. To prevent fluid and biological
tissue from flowing back to the telescope 312 or to the
25   handpiece, a castable elastomeric or thermoplastic material
is utilized to seal this area.

          FIGS. 23 and 24 illustrate this sealing material
346 and outer sheath 348 for this area of the aspirator.
This sealing material 346, generally comprising a
30   elastomeric or thermoplastic self-curing material of
relatively low hardness or durometer (i.e., less than 80
Shore A) is essential for preventing the fluid which is
desired to be removed through the lower lumen 318 from
contaminating or seeping into the handpiece of the

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aspiration unit. During the manufacture of the aspirator, after the telescope 312 is placed within the resonator channel 314, sheath 348 is placed around the joint area and the synthetic elastomeric or thermoplastic material is cast
5   there between. Preferably, this cast material is a synthetic rubber having a durometer hardness of approximately 40 Shore A. Surprisingly, while high friction losses would be expected for such an arrangement, the losses which are actually encountered are very small, because the
10 actual frequency and vibrational velocities are very low in the encapsulated area. Therefore, isolation of the handpiece of the unit from the fluids removed from the body of the patient is achieved without reducing the vibrational forces that are transmitted to the working tip of the
15 aspirator. The seal 346 also isolates the unit from the atmosphere.

Referring now to FIG. 24, it is evident that seal 340 prevents the fluids which are to be removed from the patient from flowing beneath or outside of resonator 314,
20 such as between resonator 14 and lower lumen 318. However, this seal 340 does not obviate the need for the cast sealing material 346, since the cast sealing material is used to prevent the fluid, which is in lower lumen 318 from contaminating the handpiece of the overall aspiration unit.

25 Referring now to FIGS. 25-27, there are illustrated various additional modified working tip arrangements and configurations for the resonator 314 of the invention. As shown in FIG. 27, the working tip can be of a partially blocked off channel which provides advantages with
30 respect to precision cutting of the biological material. This same effect can be achieved by narrowing the channel means by tapering the tip or by reducing the cross sectional area of other configurations, i.e., such as by gradually diminishing the cross sectional area or size of the channel

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means or by otherwise configuring the open area of working tip to be of a smaller dimension than of the the resonator 314.

5   In other embodiments, as shown by FIGS. 25 and 27, the tip may comprise part of the tubular unit which is also reduced or restricted in diameter at the working point. The end of the tube can be restricted by means of an overlap 350 or by way of a crimping on the end of the tube to restrict the outer diamter at the working point. This tubular design

10   provides an advantage wherein blockage of the resonator tube 314 is prohibited, since any removed biological material must pass through the smaller bore of the open tip to enter the tube 314. Thus, the material removed would not be able to block or clog the tube 14 when suction is used to

15   withdraw such removed biological material.

While it is apparent that the invention herein disclosed is well calculated to fulfill the objects above stated, it will be appreciated that numerous modifications and embodiments may be devised by those skilled in the art,

20   and it is intended that the appended claims cover all such modifications and embodiments as fall within the true spirit and scope of the present invention.

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CLAIMS

What is claimed is:

1. A vibration apparatus comprising

a vibration source for vibrating at a high frequency and with a first amplitude;

a first transformer having an input end and an output end, the input end being coupled to the vibration source to be vibrated thereby, and the output end vibrating in response to such received vibrations with a second amplitude greater than such first amplitude; and

a second transformer having an input end and an output end, the input end being coupled to the output end of the first transformer to be vibrated thereby, and the output end vibrating in response to such received vibrations with a third amplitude greater than such second amplitude, the second transformer being elongated and when vibrating having a substantially constant mechanical stress level in substantially all of its length.

2. The vibration apparatus of claim 1 further comprising a handpiece wherein said vibration source is mounted in the handpiece and said first transformer input section is relatively large in cross-sectional area and said first transformer output section is being relatively small in cross-sectional area.

3. The vibration apparatus of claim 1 or 2 wherein the first and second transformers and the vibration source are elongated and have longitudinal axes and at least part of the first transformer is curved to offset the longitudinal axis of the second transformer from the longitudinal axis of the vibration source by a selected angle of offset.

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4.   The vibration apparatus of claim 1, 2, or 3
wherein the vibration source and the two transformers vibrate
extensionally with alternating vibrational nodes and
antinodes occurring therein, the vibration source is mounted
5   in the handpiece by flexible means between the interior of
the handpiece and the vibration source at a vibrational node
of the vibration source, and the first transformer is mounted
in the handpiece by flexible means between the interior of
the handpiece and the first transformer at a vibrational node
10   of the first transformer, the latter vibrational node being
near the point of connection between the input and output
sections of the first transformer.

5.   The vibration apparatus of claim 2, 3, or 4
15   further comprising viewing means mounted in the handpiece for
viewing from the handpiece a work site adjacent the output
end of the second transformer.

6.   The vibration apparatus of claim 5, wherein
20   said viewing means is elongated, extends from the handpiece
to such work site along a path closely parallel to said
second transformer and said output section of said first
transformer, and passes through a groove formed in said input
section of said first transformer.

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7.   An endoscopic ultrasonic aspirator comprising:
a hollow handpiece;
an elongated sheath having a hollow bore
communicating with the interior of the handpiece and having a
30   working end away from the handpiece;
a vibration source within the handpiece for
producing mechanical vibrations in response to an alternating
current supplied to said vibration source;
means for supplying such alternating current

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to said vibration source;

elongated tool means coupled to the vibration source and passing through the hollow bore of the sheath to a work site beyond the working end of the sheath for
5   transmitting such mechanical vibrations to such work site;

viewing means extending from the handpiece to such work site for providing a view from the handpiece of such work site;

means for supplying fluid to a fluid space
10   defined between said tool means and said hollow bore of said sheath; and

fluid detection means for detecting the presence of fluid in the fluid space and connected to the means for supplying alternating current for terminating such
15   supplied alternating current and thereby stopping such mechanical vibrations when such fluid is not present.

8.   The apparatus of claim 7, wherein the fluid detection means includes electrical means coupled to the
20   fluid space for sensing the electrical capacitance in the fluid space and terminating such supplied alternating current when the capacitance is above a predetermined level to indicate that fluid is not present.

25   9.   An apparatus as in claim 8, wherein said electrical means includes a conductive probe, and said capacitance is measured between said probe and said tool means.

30   10.   An apparatus as in claim 9, wherein said probe is located within the sheath and runs substantially parallel with the tool means.

11.   An apparatus as in claim 9, wherein

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the viewing means extends through a second bore in the sheath
that is not exposed to fluid from said fluid space; and
the probe is located within said second bore.

5   12.   The apparatus as in claim 7, 8, 9, 10 or 11
wherein said tool means and said working tip means each
comprise open channel means and means for supporting said
open channel means in the form of a resilient plug and which
further comprises means for sealing the couple between said
10   open channel means and said vibration source.

            13.   The apparatus as in claim 7, 8, 9, 10 or 11
wherein said tool means comprises cylindrical tubular means
and said working tip means is smaller in bore diameter than
15   said cylindrical tubular means by being tapered, crimped or
obstructed along its outside diameter to provide said
smaller bore.

            14.   An apparatus for removal of unwanted
20   biological material comprising:
                  (a)   a handpiece;
                  (b)   an elongated sheath extending from the
handpiece and having a hollow bore therethrough;
                  (c)   the vibration apparatus of claim 1, 2, 3,
25   4, or 5 located in the handpiece; the first and second
transformers being located in the hollow bore within the
sheath and spaced therefrom, the second transformer being
coupled to the first transformer for amplifying vibrations
thereof to a sufficient velocity to disintegrate such
30   unwanted tissue;
                  (d)   said second transformer having a working
tip extending beyond the end of the sheath away from the
handpiece;
                  (e)   said vibration source and said two

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transformers being elongated and having a continuous hollow
bore extending along a common longitudinal axis thereof,
thereby forming:

(i) a first fluid passage in a space
5   defined between the transformers and the sheath; and

(ii) a second fluid passage along said
common longitudinal axis;

(f)   means for introducing fluid into one of
said fluid passages to irrigate an operating site adjacent
10 the working tip of the second transformer; and

(g) means for applying suction to the other
of said fluid passages to remove such fluid and such
disintegrated unwanted tissue from such operating site.

15   15.   An apparatus as in claim 14, wherein said
means for applying suction to said other fluid passage
includes

hose means for receiving such fluid and
tissue;
20   biopsy valve means coupled to said hose means
for selectively diverting fluid and tissue out of said hose
means;

biopsy trap means for receiving such fluid and
tissue selectively diverted out of said hose means to filter
25 selected tissue therefrom; and

pump means for applying suction force to said
biopsy trap means and to said hose means.

16.   An apparatus as in claim 15, further
30 comprising main trap means for receiving such fluid and
tissue that is not selectively diverted out of the hose
means, and wherein said working tip is blunt.

17.   The apparatus of claim 14 or 15 wherein said
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working tip further comprises open channel means to facilitate viewing of said tip during use of the aspirator.

18.   The apparatus of claim 14, 15 or 16 wherein the entire length of the continuous hollow bore of said vibration source and transformers is configured and dimensioned in the form of open channel means so as to partially receive, hold, and support said viewing means, thus minimizing the size of said aspirator.

19.   The apparatus of claim 17 or 18 wherein said open channel means has a U or V cross-sectional configuration.

20.   The apparatus of claim 14, 15 or 16 wherein said working tip means extends beyond the end of the sheath away from the handpiece; said working tip means of smaller dimension than the output end of said second transformer.

21.   The apparatus of claim 20 wherein said second transformer comprises first cylindrical tubular means and said working tip means comprises second cylindrical tubular means of smaller diameter than said first tubular means.

22.   The apparatus of claim 20 wherein said second transformer tapers and diminishes in diameter to the dimension of the smaller diameter second tubular means.

23.   A method of removing cellular material from a compliant tissue relatively deep within a biological body through a narrow orifice comprising:
          inserting an apparatus according to one of claims 8 through 22 into the orifice with the working tip thereof located close to the material to be removed; and

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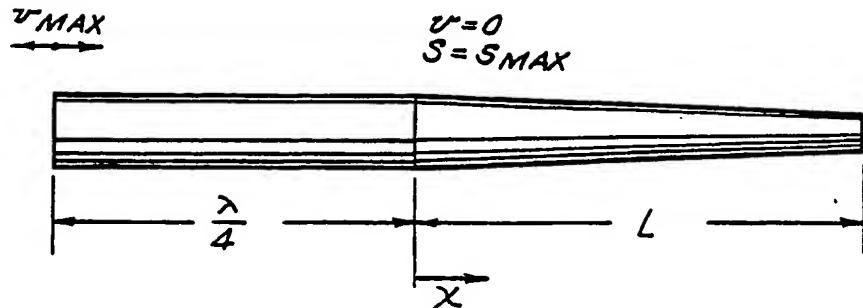
F I G. 1
HIGH VELOCITY ULTRASONIC
EXTENSIONAL RESONATOR
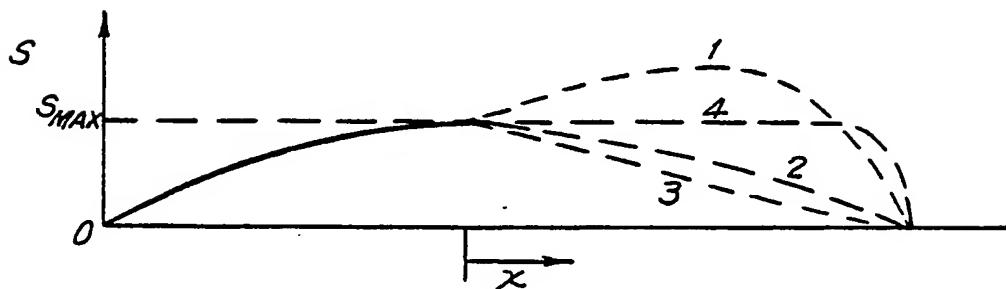
F I G. 2
STRESS DISTRIBUTIONS FOR VARIOUS
CROSS SECTION AREA VARIATIONS
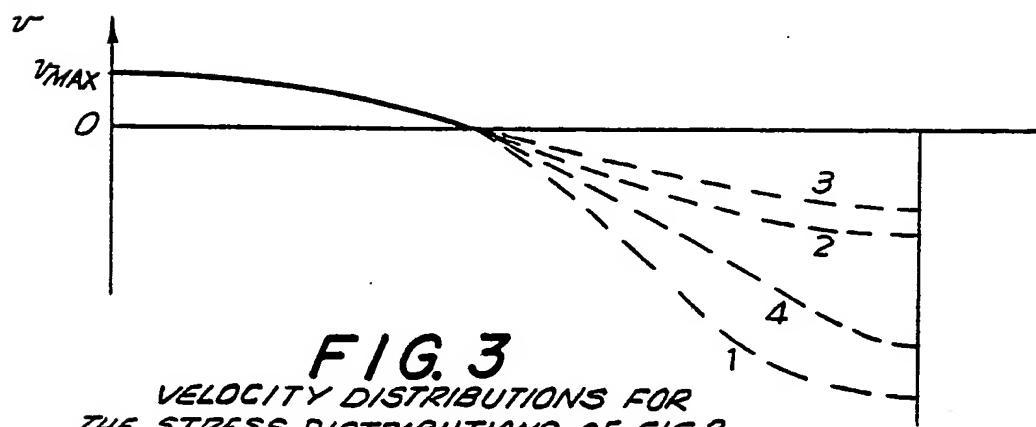
F I G. 3
VELOCITY DISTRIBUTIONS FOR
THE STRESS DISTRIBUTIONS OF FIG. 2
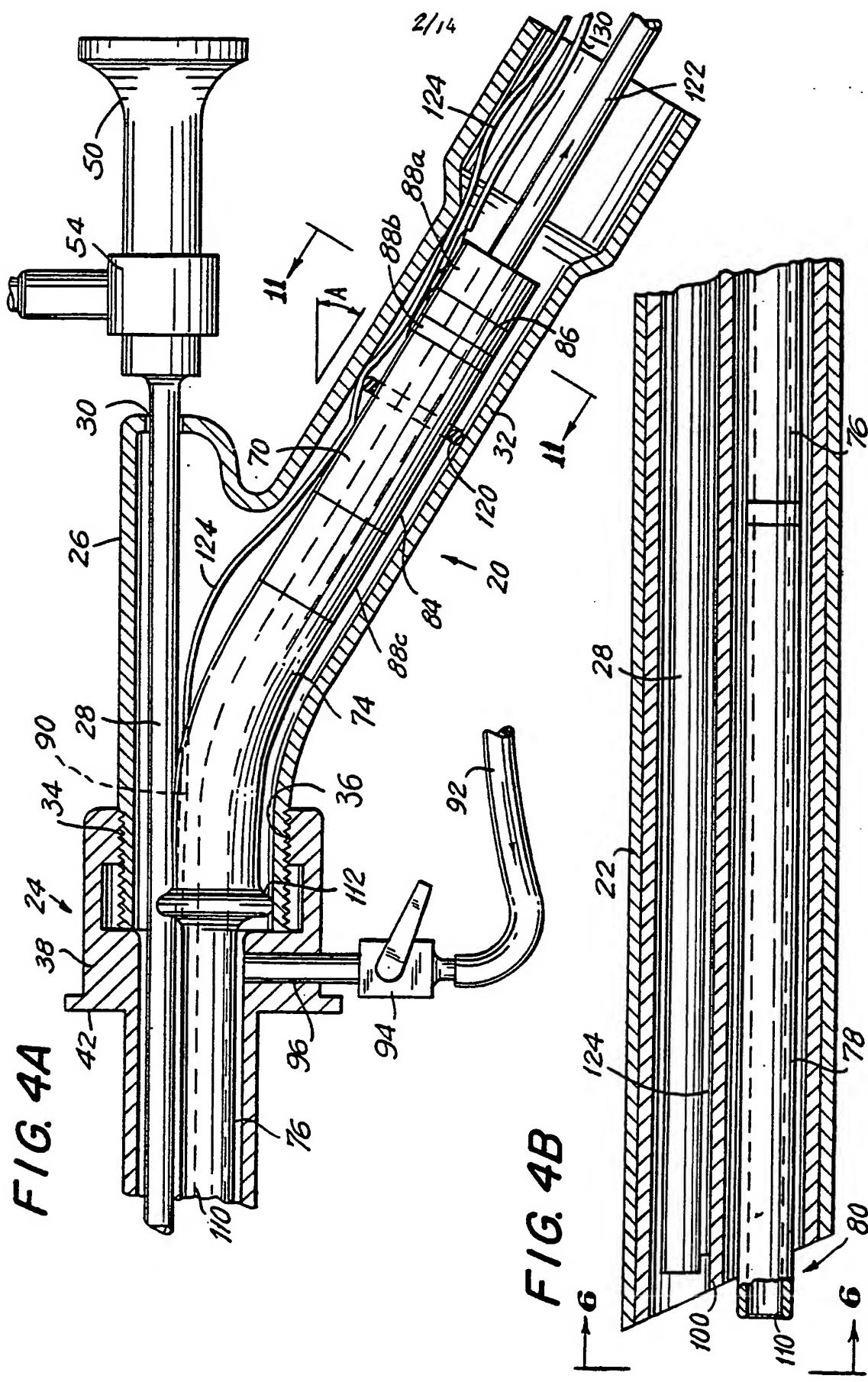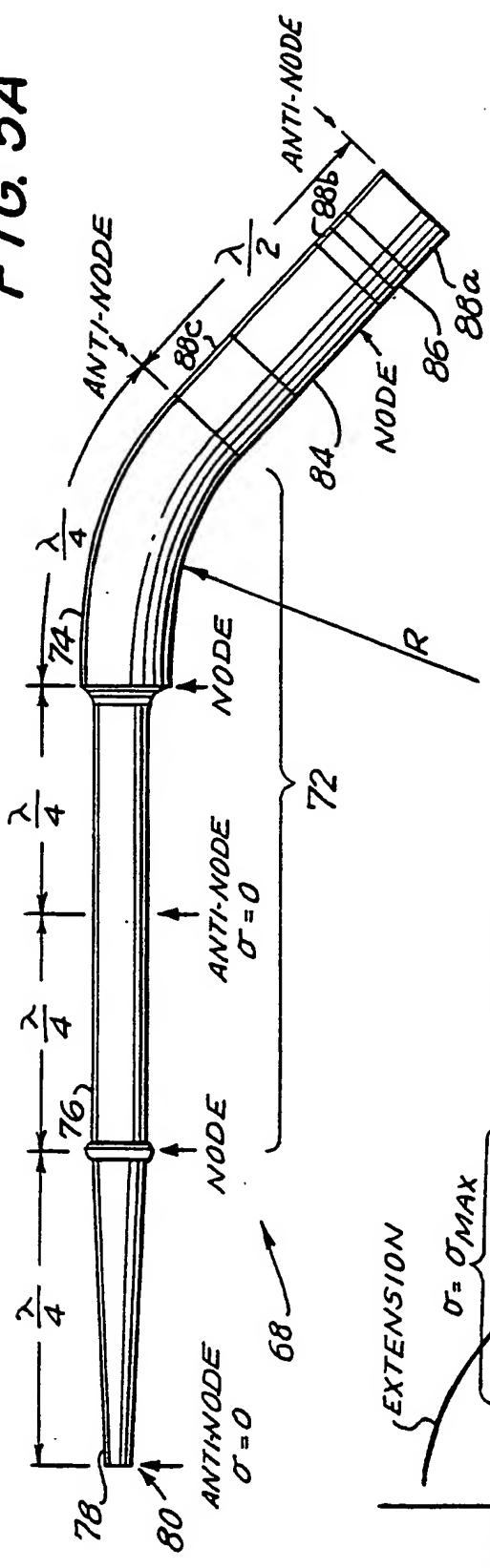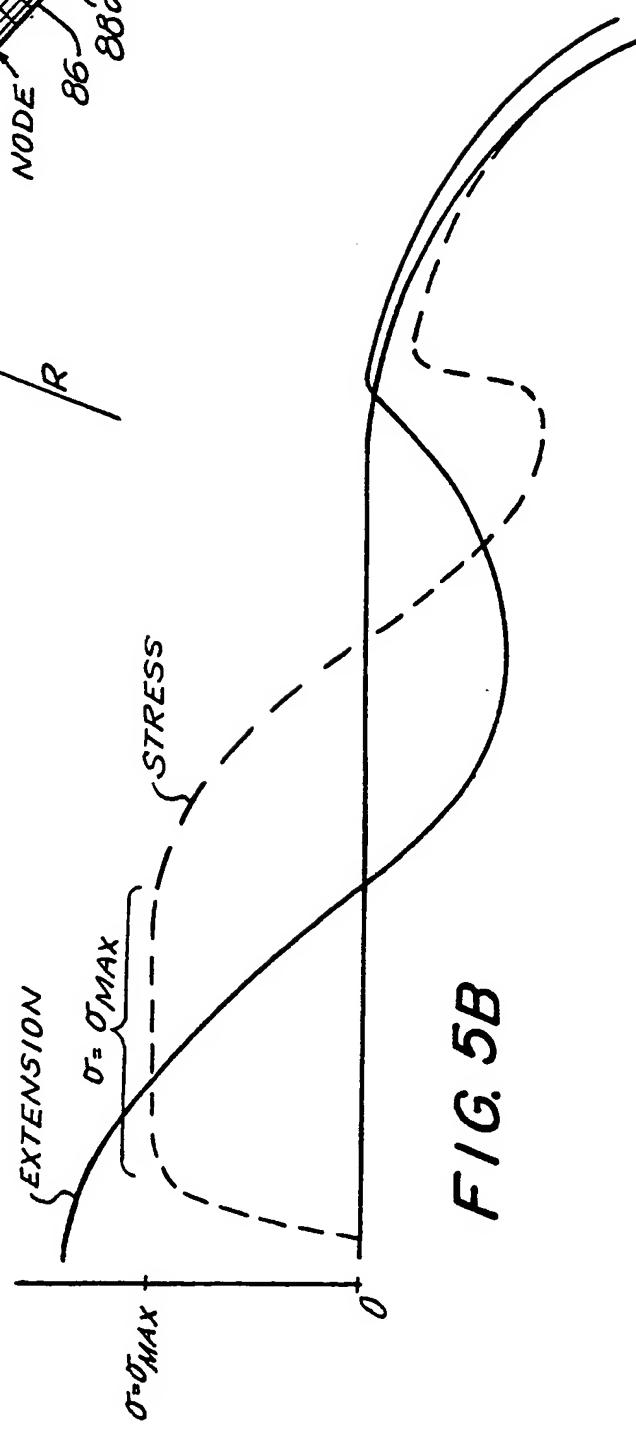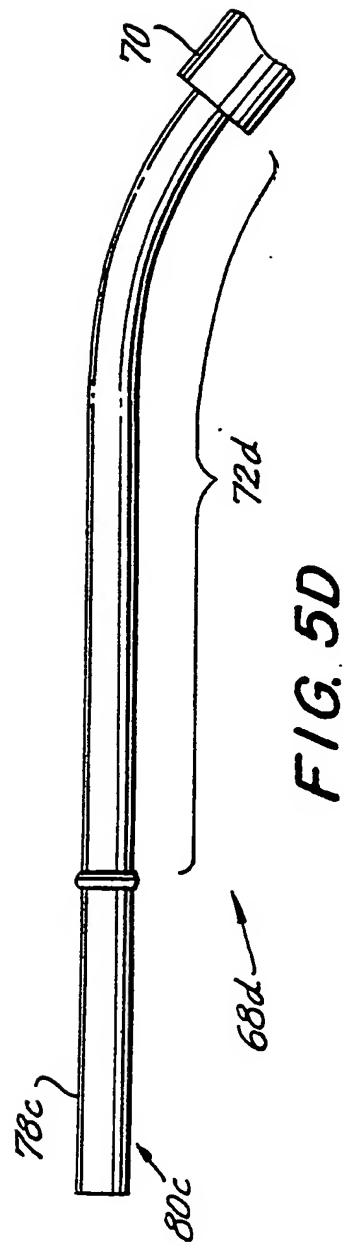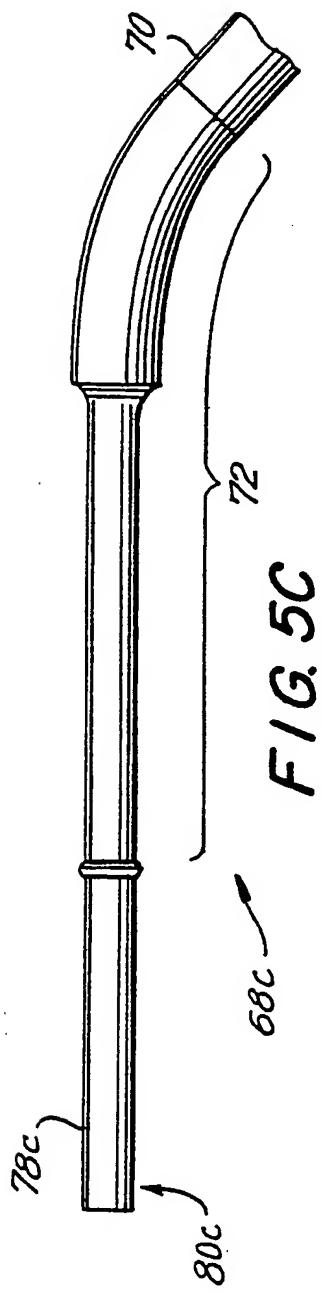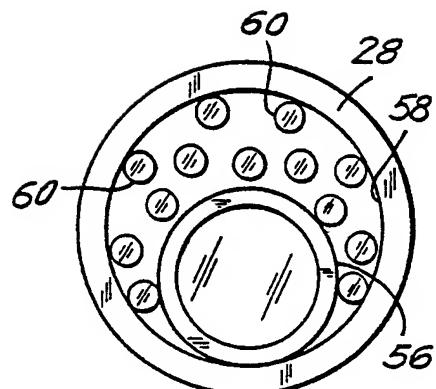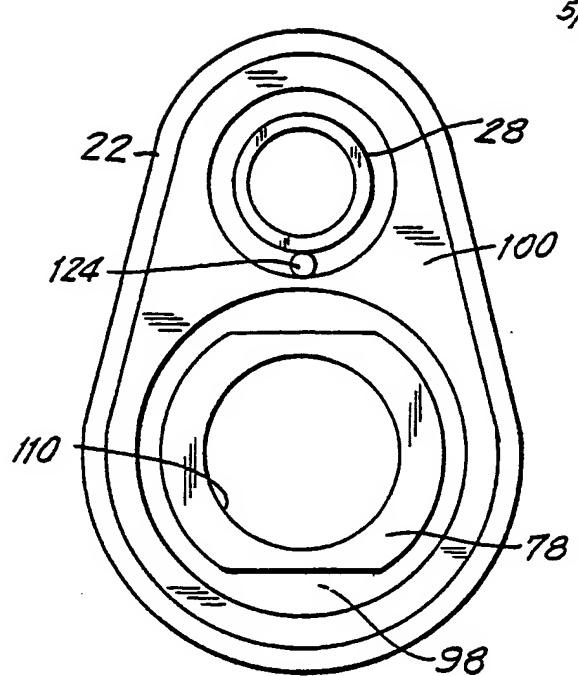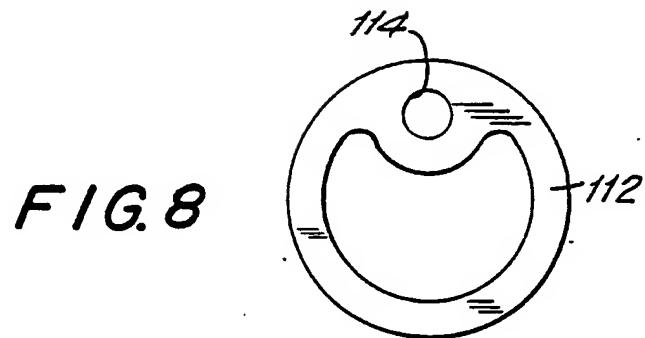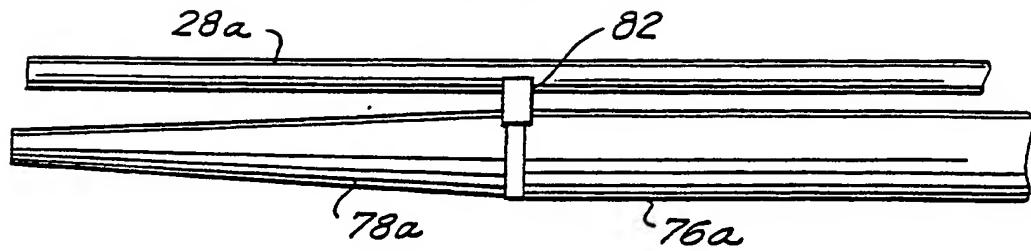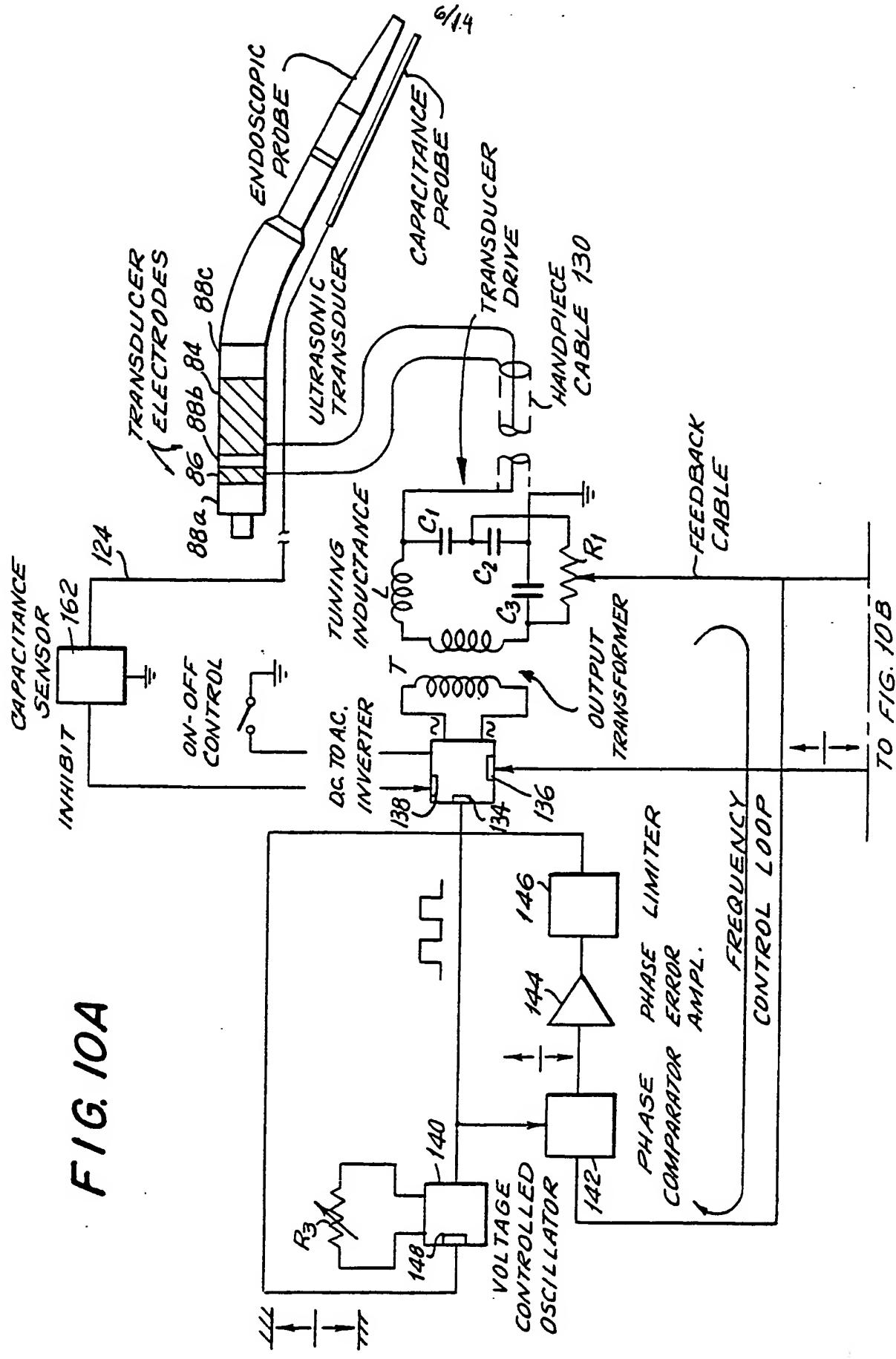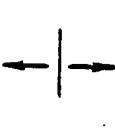
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FIG. 4A

FIG. 4B

FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

FIG. 6

FIG. 7

FIG. 8

FIG. 9

FIG. 10A

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FIG.IOB

FIG. 12A

IRRIGATION SUPPLY 170

ILLUMINATOR CONNECTION

EYE PIECE 50

54

32

92

IRRIGATION VALVE 94

SHEATH 22

ULTRASONIC TIP 80

TELESCOPE 28

19cm

1·2m

FIG. 11

116

110

88b

71

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FIG. 12B

ASPIRATION TRAP 180

VACUUM SWITCH 194

CHECK VALVE 186

VENTING VALVE 198

SOLENOID PINCH VALVE (NORMALLY CLOSED) 196

TO SYSTEM ELECTRICAL CONTROL

SOLENOID PINCH VALVE (NORMALLY OPEN) 202

ASPIRATION VALVE 200

ASPIRATION PUMP 210

WASTE FLUID COLLECTOR 220

BIOPSY TRAP 176

BIOPSY VALVE 122

ASPIRATION 122

ULTRASONIC POWER LEADS 130

CAPACITANCE PROBE LEAD 124

0.3-0.5m
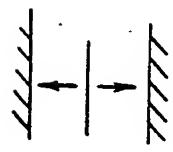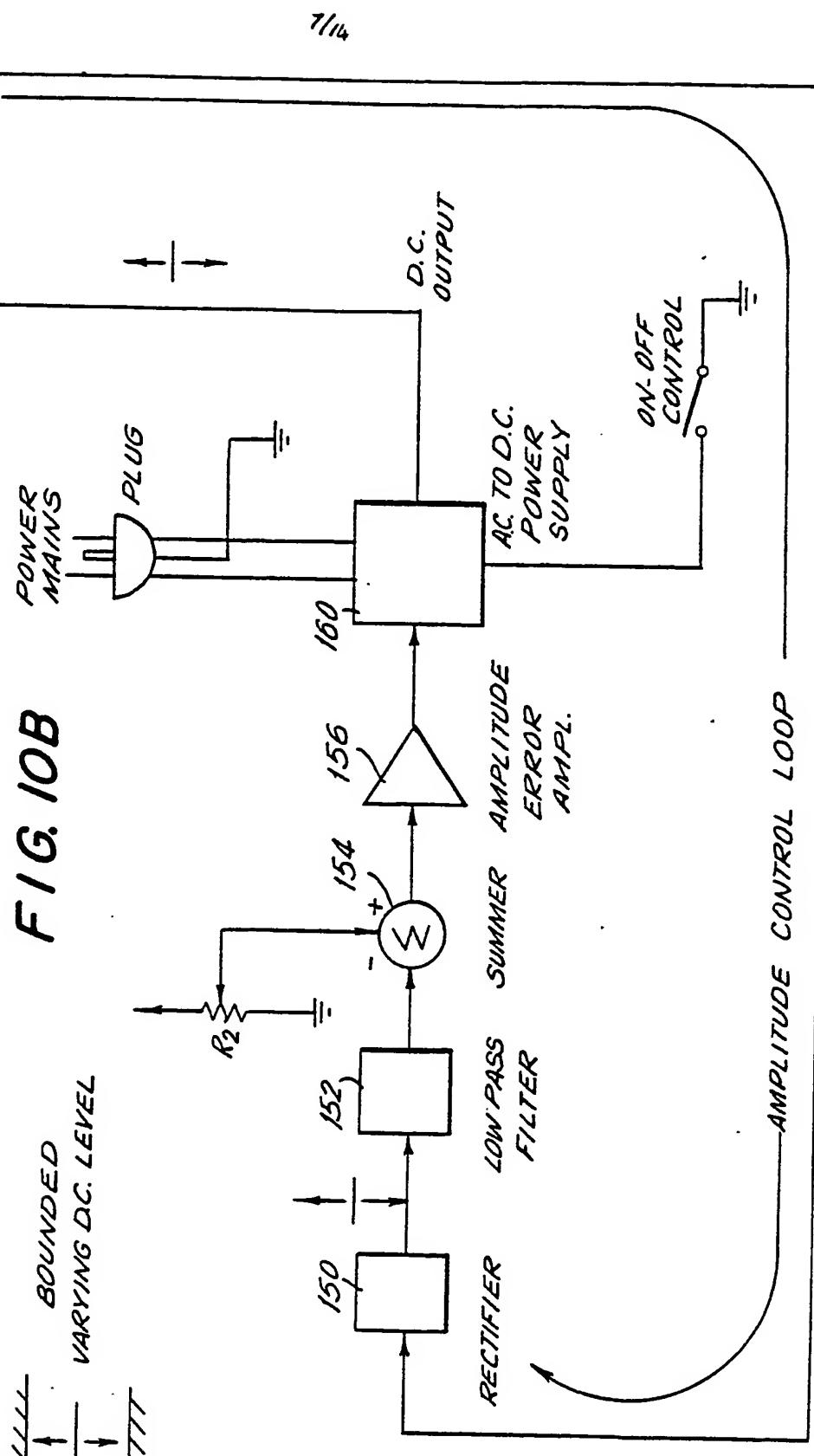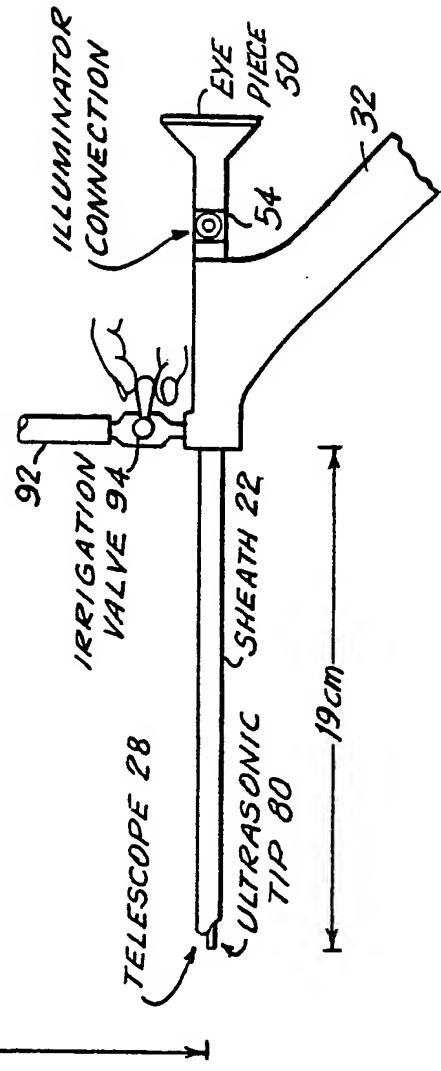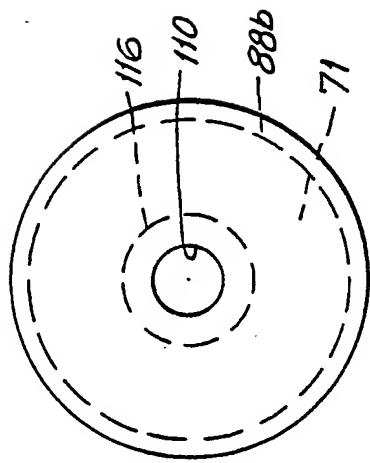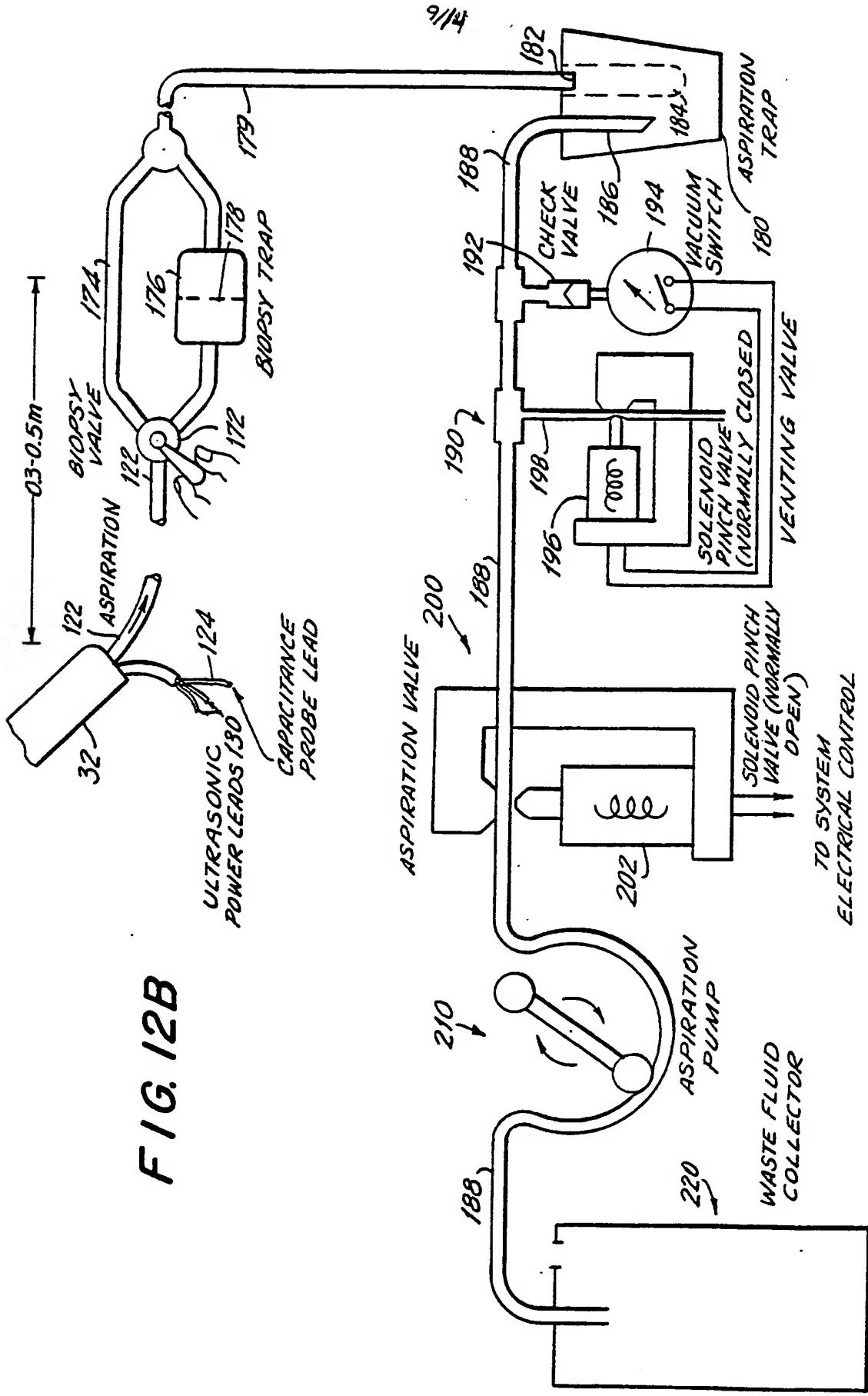
FIG. 13
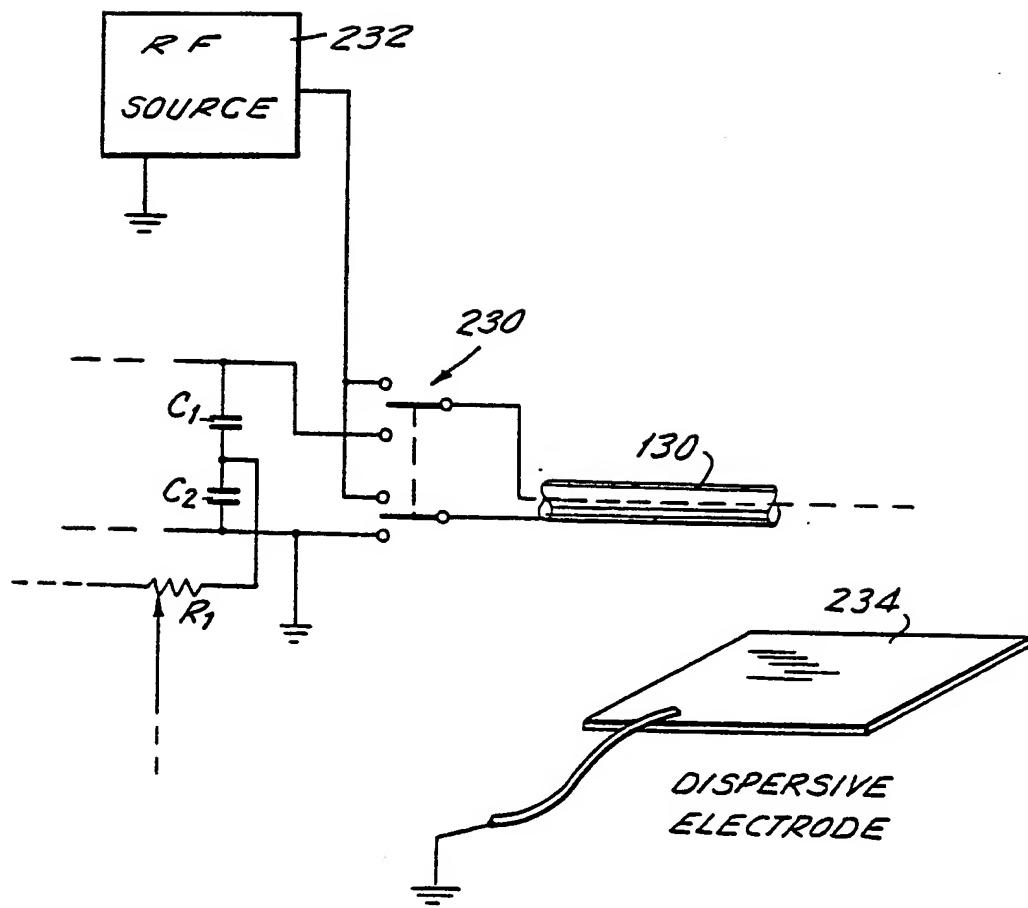
FIG. 14
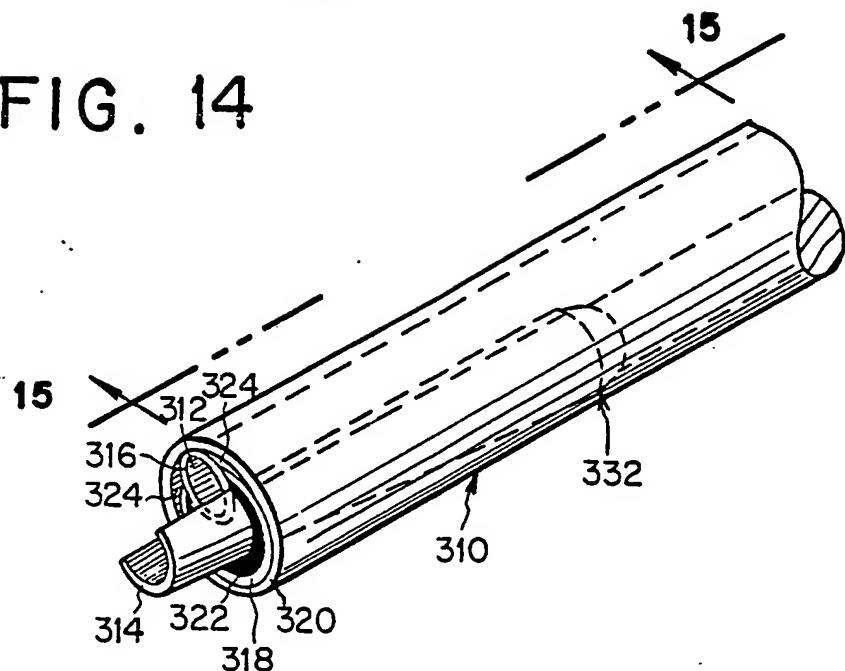
FIG. 15

FIG. 16   FIG. 17   FIG. 18
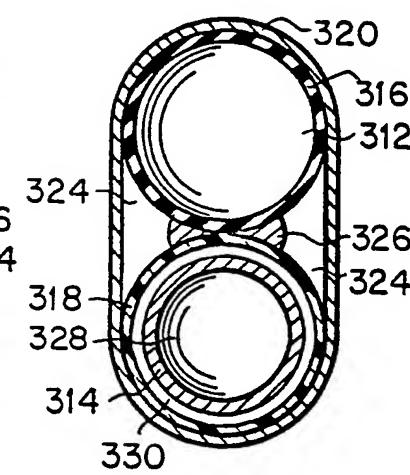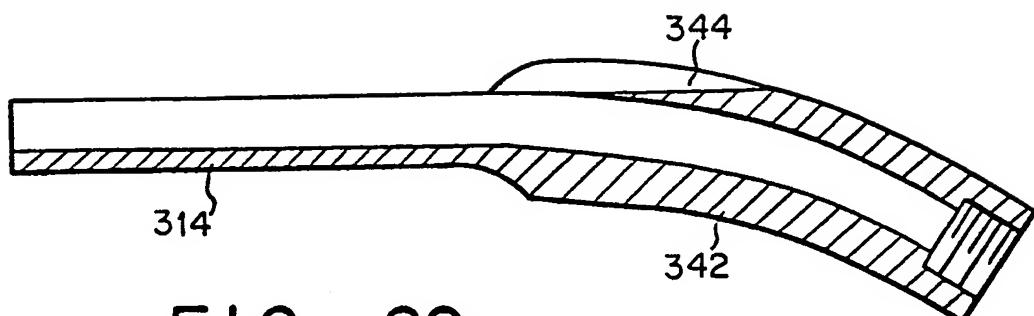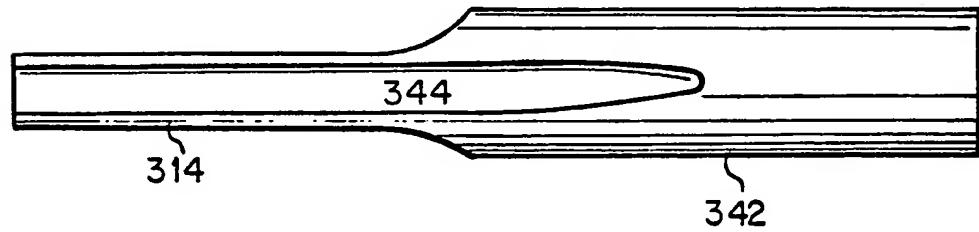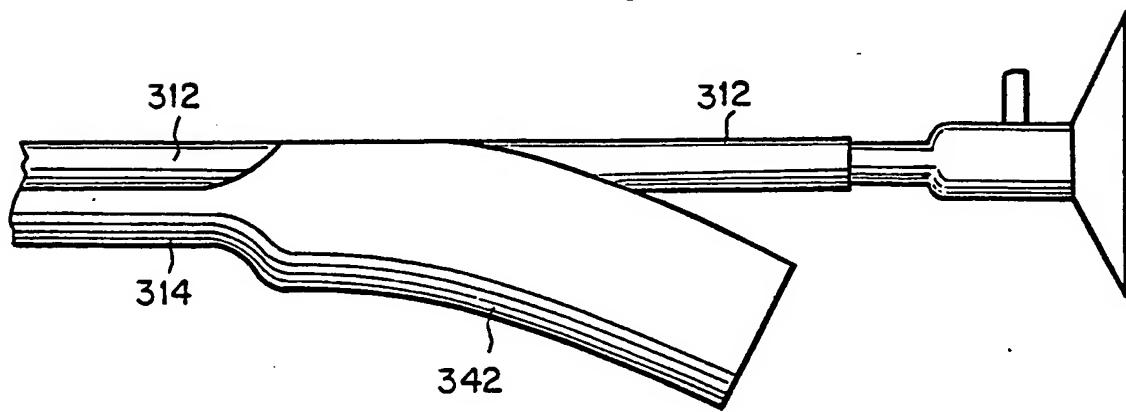
FIG. 19

FIG. 20

FIG. 21

FIG.22
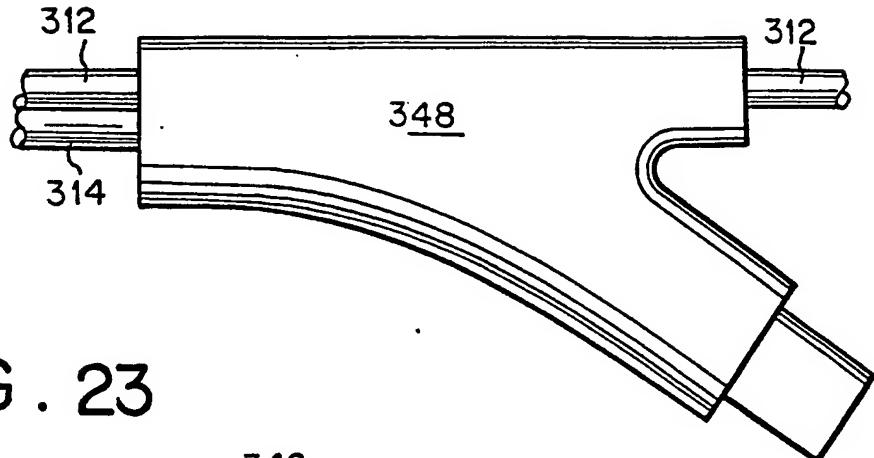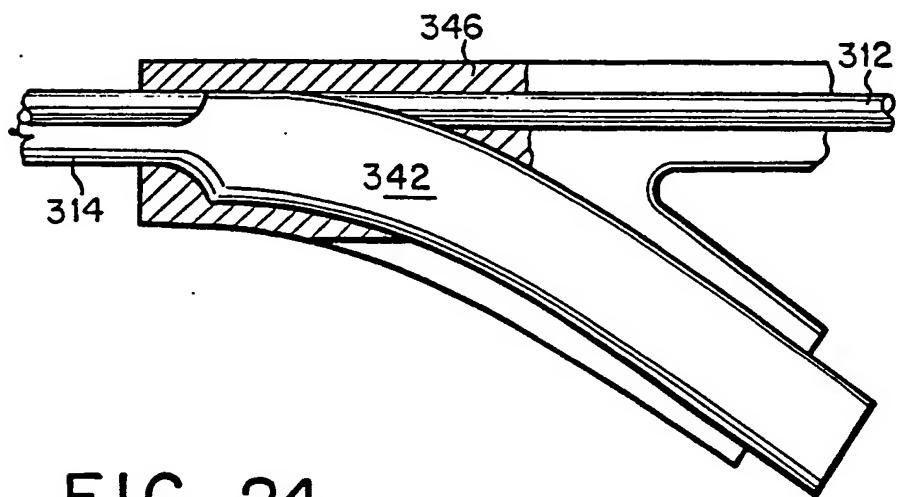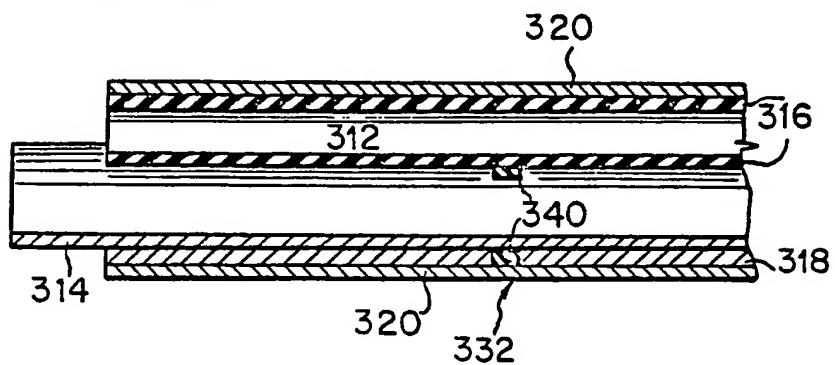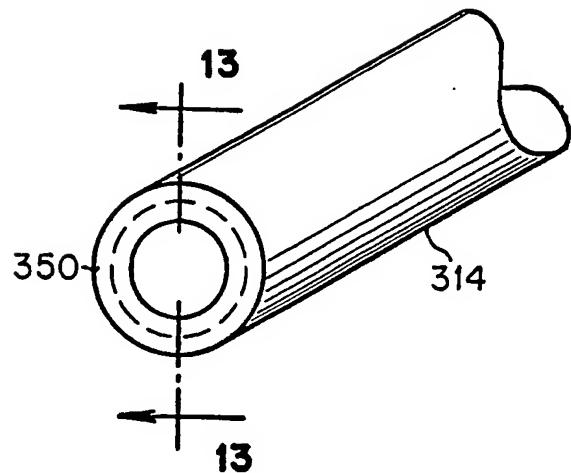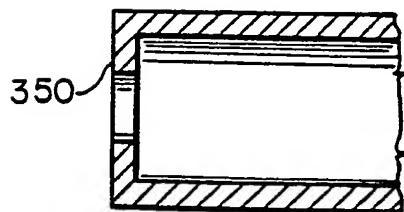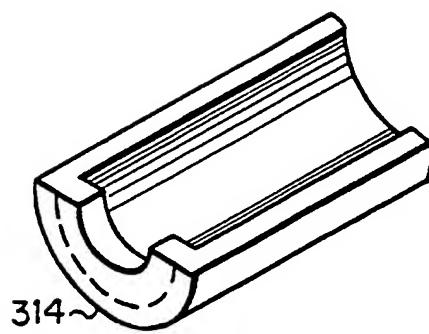
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FIG.23

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FIG.24

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FIG. 25

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FIG. 26

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FIG. 27

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INTERNATIONAL SEARCH REPORT

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³

According to International Patent Classification (IPC) or to both National Classification and IPC

U.S. Cl. 128/24 A   IPC(4): A 61 H 21/00

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System	Classification Symbols
U.S.	128/24A, 24.2, 24.5, 32, 303.15, 328 604/22, 27, 35, 43, 119

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
Y	US, A, 4,425,115 (KUCHINICH) 10 January 1984. See the entire document.	1-5, 14-15 20-23
Y	US, A, 3,133,351 (VON SEGGERN) 11 January 1964. See column 8, lines 43-61.	3
Y	US, A, 2,227,727 (LEGGIADRO) 7 January 1941. See the entire document.	5
Y	US, A, 4,136,700 (BROADWIN ET AL) 30 January 1979. See the entire document.	15

* Special categories of cited documents: ¹⁵

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION	
Date of the Actual Completion of the International Search ² 30 October 1986	Date of Mailing of this International Search Report ² 1 3 NOV 1986
International Searching Authority ¹ ISA/US	Signature of Authorized Officer ²⁰ *Randy Citrin* Randy Citrin

Form PCT/ISA/210 (second sheet) (May 1986)